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Senate Hearings

Before the Committee on Appropriations

MF 72

Departments of:
—Labor
—Health and Human Services
—Education
—and Related Agencies Appropriations

ORIGINAL

Fiscal Year 1986

99th CONGRESS, FIRST SESSION

H.R. 3424

PART 2—(Pages 1-1486)
DEPARTMENT OF HEALTH AND HUMAN SERVICES

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S. Hrg. 99-302, Pt. 2

DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

HEARINGS

BEFORE A

SUBCOMMITTEE OF THE

COMMITTEE ON APPROPRIATIONS UNITED STATES SENATE

NINETY-NINTH CONGRESS

FIRST SESSION

ON

H.R. 3424

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1986, AND FOR OTHER PURPOSES

PART 2—(Pages 1-1486)

Department of Health and Human Services

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

TUESDAY, MARCH 5, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:40 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Specter, Proxmire, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. MARGARET M. HECKLER, SECRETARY

OPENING REMARKS

Senaor WEICKER. With this morning's hearing, the subcommittee enters the second major phase of its review of fiscal year 1986 administration budget requests. Beginning today, the Department of Health and Human Services comes before us to discuss how the administration is proposing to help those in our society who are most in need.

I welcome Secretary Heckler at our hearing, and I look forward to her testimony.

Through the Secretary's testimony, and that of her subordinates during the 8 days of hearings this month, the subcommittee will determine whether the most basic human needs of our society are the cause or the casualty of the administration's fiscal proposals.

PREPARED STATEMENT

Madam Secretary, before you proceed we will insert your statement in the record.

[The statement follows:]

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STATEMENT OF HON. MARGARET M. HECKLER

The budget for fiscal year 1986, which I present to you this morning, is the culmination of many months of serious and honest debate about public policy priorities for this Nation. For the Department of Health and Human Services, the result is a balanced plan which offers opportunities for restraining growth in spending as an integral part of the President's goal of reducing the Federal deficit and that gives clear priority to maintaining essential benefits for the Nation's most vulnerable individuals and families -- the poor, elderly, and disabled.

The single greatest domestic problem facing the United States of America in 1985 is the necessity of reducing the Federal deficit. Mr. Chairman, unless you and I and other members of the Congress and the Executive Branch take affirmative action to reduce the deficit, it will be $230 billion in fiscal year 1986.

The policies embodied in the President's budget will reduce this deficit and overall Federal spending by approximately $50 billion. The Health and Human Services share of this amount is $7.5 billion or 15 percent--far less than this Department's 34 percent share of total Federal spending. It is also less than the $9.7 billion in savings proposed for the Department of Defense.

I know that budget reduction is not an easy task. It was difficult for us and it will be difficult for this Committee. But in making these budget decisions, we have not sacrificed the compassionate goals of Health and Human Services--service to the poor, the handicapped, the ailing, and the aged in our society. The President has come down on the side of the safety net: the basic needs of the poor, the infirm, and those who through no fault of their own need our help have been protected in this budget.

To meet this commitment, HHS will spend a total of $330.3 billion in 1986 including outlays from the Social Security and Medicare Trust Funds, as well as from Federal funds appropriated by the Congress. For the Department's programs considered by this Subcommittee, our appropriations request for 1986 totals $79.7 billion. I will emphasize this appropriations request in the remainder of my remarks.

PUBLIC HEALTH SERVICE

For the programs of the Public Health Service (PHS) within this Subcommittee's purview, we are requesting $7.6 billion in 1986. These funds will be used to help Americans achieve improved health status by supporting biomedical research, conducting disease investigations, implementing health promotion practices, and assisting States to deliver health services.

HEALTH RESOURCES AND SERVICES ADMINISTRATION

A total of $1,157 million is requested for activities of the Health Resources and Services Administration (HRSA). Highlights of the 1986 HRSA budget include:

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o National Health Service Corps (NHSC)

The $50 million request for the NHSC will support a total field strength of 3,507 physicians and other health professionals, including 570 Federally-salaried assignees in 1986. The program continues an emphasis on encouraging individuals to fulfill NHSC scholarship service obligations in health manpower shortage areas through private practice instead of as Federal employees. Between 1982 and 1985, a total of 3,949 health practitioners have participated in private practices, and as a result, Federal program costs were reduced.

o Maternal and Child Health and Primary Care Block Grants

The budget includes $478 million for the Maternal and Child Health and $550 million for the Primary Care block grants. Concurrent with the budget request is a legislative proposal to consolidate the Family Planning, Migrant Health and Black Lung categorical grant programs into an expanded Primary Care block grant to assist States to meet local health services priorities.

o Health Professions Education

In view of steadily increasing supplies of physicians and nurses, projected national surpluses in these occupational fields, and the improved distribution of health care practitioners to medically underserved areas, no funds are requested in 1986 for the Health Professions education programs. These Federal subsidies were initiated 20 years ago to alleviate personnel shortages existing at that time. We have successfully accomplished this goal, and the time has come to phase out Federal support of these programs.

Needy students requiring financial aid to complete their education will continue to have access in 1986 to an estimated $67 million in health profession and nursing student loan revolving funds, as well as $100 million in Health Education Assistance Loan (HEAL) guarantees.

o Health Planning

No funds are requested for Health Planning in 1986. This Administration has consistently advocated the elimination of Federal funding for State and local planning activities because of the program's relative ineffectiveness in controlling health care cost increases.

CENTERS FOR DISEASE CONTROL

The 1986 budget continues to emphasize health promotion and disease prevention in order to reduce the spread of disease, encourage healthy life styles, and help control health care costs.

For the principal prevention agency, the Centers for Disease Control (CDC), the 1986 budget request is $392 million. The $16 million decrease from 1985 is due to the elimination of lower priority programs for which alternative sources of funding are more appropriate, and because of minor reductions in administrative and Federal salary costs.

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o Immunization

In 1986, $54 million is requested for the immunization program, the same level as in 1985. Through CDC leadership and provision of financial assistance to States, immunization levels of school-aged children have reached 97 to 98 percent, and many childhood diseases, such as measles, mumps, rubella, tetanus and polio have been brought under control.

The request also includes $4 million to continue purchasing and stockpiling children's vaccines. This important multi-year initiative will provide access to an emergency supply of these vaccines in case of a stoppage in domestic production. Once current spot-shortages of diptheria-pertussis-tetanus (DPT) vaccines are eased and a predictable supply stream is reestablished, CDC will purchase DPT vaccines for the stockpile inventory.

o Aquired Immunodeficiency Syndrome (AIDS)

Over the past three years, this Department has supported a major research effort to determine the cause of AIDS, to determine its frequency and distribution in the population, to develop the means for preventing this disorder, and to improve the diagnosis and treatment of AIDS. Success has occurred with the identification of HTLV-III as the underlying cause of AIDS, and, as a result, we will soon be able to detect antibodies of HTLV-III in blood and blood products. To continue this effort, $86 million in total Departmental resources (including $19 million in CDC) is requested in 1986 for AIDS research and investigations, compared to $96 million in 1985, $61 million in 1984, and $29 million in 1983. The decrease in 1986 is due to one-time costs in 1985 for blood supply studies and facility construction and renovations in FDA and CDC.

NATIONAL INSTITUTES OF HEALTH

The 1986 request for the National Institutes of Health (NIH) is $4.9 billion. This budget will continue support for basic health research that will be translated into future long-term improvements in medical care and the health of the American people.

Research will continue to be pursued during this period of rapid advancements in the life sciences in such priority areas as Alzheimer's disease, molecular genetics, immune system research, diagnostic brain imaging, and development of a vaccine for AIDS. In addition, studies on low birth weight of infants and preventive strategies for many major diseases - stroke, epilepsy, and central nervous system trauma - will be enhanced.

o In 1986, $2.6 billion is requested to fund 5,000 new and competing research project grants and nearly 11,250 continuation grants. In addition, 646 projects which were funded from 1985 appropriated funds will continue in 1986. Research project grants support individual research scientists who are the primary source of fundamental biomedical discoveries. Continued priority is given this key mechanism.

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The budget request is sufficient to provide an estimated 8 percent increase in average research project grant awards. Payments for indirect costs to research grantees will be frozen at the 1985 rate.

In 1985, in view of the compelling need to control increasing Federal expenditures and still maintain a predictable and reasonable level of research support, NIH will award in 1985 an estimated 646 of the 5,000 new research projects and 45 of the 500 research centers on a multi-year basis. Without such forward funding, it would have been necessary to propose a significant reduction in the number of new and competing awards in 1986. The one time use of multi-year awards will allow the initial and subsequent continuation costs of these projects to be spread over a three-year period, but funded fully from 1985 appropriated funds. The funding of 5,000 new projects annually continues a policy of research stability supported by this and previous Administrations.

- o $217 million is requested in 1986 to support an estimated 9,900 research trainees, roughly comparable to the level of trainees supported each year over the past decade.

- o $412 million is included in the request to support 500 research centers, approximately the same number that has been supported over the past several years. Of these, 45 will be supported from 1985 appropriated funds.

- o All other research mechanisms, such as contracts, disease control awards, and intramural research, are maintained in 1986 at essentially the 1985 level of $1.5 billion. In addition, the request includes $10 million to continue efforts to stimulate health research at minority and other smaller schools which previously have received little or no NIH funding. Within this request the shared instrumentation program and the biomedical research technology program will also be continued at approximately the 1985 level.

ALCOHOL, DRUG ABUSE AND MENTAL HEALTH ADMINISTRATION

A total of $929 million is requested in 1986, a decrease of $39 million from the 1985 level, for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA) to support basic and behavioral research, training, and services to States. Included in this total is $490 million for the Alcohol, Drug Abuse and Mental Health Block Grant, the same amount as was available in 1985.

- o Similiar to NIH, priority in ADAMHA will be placed on funding 500 new and competing research project grants and 782 continuation grants. Stability of research funding in ADAMHA is also an important priority of this Administration. Together with the 38 grants whose 1986 costs will be continued from 1985 appropriated monies, a total of 1,320 research projects will receive support from ADAMHA in 1986.

Emphasis will be placed on research in the neurosciences and addressing the major problem areas of schizophrenia and depression, drug abuse studies on the "reinforcing" centers of

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the brain, the biological mechanisms involved in the susceptibility of alcoholism, and prevention efforts including the prevention of drunk driving.

- o No funds are requested for the Clinical Training Program, since overall shortages of personnel no longer exist.

- o Management improvements and administrative reductions will allow ADAMHA to save $6 million.

St. Elizabeths Hospital

In 1986, the Federal subsidy to St. Elizabeths Hospital will be $43 million, $6 million less than in 1985, reflecting the fourth year of a planned ten-year phasedown of the direct Federal subsidy for the care of District residents. The budget reflects the assumption that this decrease will be offset primarily by increased payments from the District of Columbia. Last year, legislation (P.L. 98-621) was enacted which provides for the direct transfer of the hospital to the District on October 1, 1987. By 1992, the District will pay the full cost of care for its residents.

OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

The 1986 request is $202 million for programs in the Office of the Assistant Secretary for Health. Within the request the following priority activities will be supported:

- o$16 million for health services research activities to assess the frequency of use and cost of health care, examine and improve health care delivery methods, and test the appropriateness of emerging and frequently used technologies.

- o $48 million for the National Center for Health Statistics to collect, analyze and disseminate nation-wide data on illness, health resources, and vital statistics. Within the request, $4 million will be used to plan and develop the next cycle of the National Health and Nutrition Examination Survey.

- o $8 million is included in the budget to foster the development of disease prevention and health promotion measures, with continued emphasis on bringing to the public a greater awareness of the hazards of smoking.

HEALTH CARE FINANCING ADMINISTRATION

The total 1986 HCFA budget request for Medicare, Medicaid and related programs includes outlays of $90.9 billion, an increase of $1.6 billion, or 2 percent, over the current estimate for 1985. Approximately 50 million beneficiaries will be served through the Medicare and Medicaid programs in 1986.

This budget reflects the Administration's continued commitment to constrain rising Federal health care expenditures while meeting the needs of the elderly, disabled, and poor. Although the rate of inflation in health care costs has declined during the past few years, these costs are still growing about one and a half times as fast as the general rate of inflation.

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To moderate these cost increases, the budget request includes a number of legislative and regulatory proposals designed to slow the rate of growth in program expenditures. These proposals, estimated to save the Medicare and Medicaid programs $5.3 billion in 1986, are part of a government-wide effort to limit Federal outlays.

For HCFA programs which require appropriations action--primarily Medicaid and a portion of the Medicare program--we are requesting appropriations of $44.0 billion in 1986.

MEDICAID

Medicaid appropriations of $23.7 billion are projected for 1986, $1.8 billion more than 1985. This includes $6.0 billion provided in advance appropriations for the first quarter of 1986. Also, $6.5 billion is requested for the first quarter of 1987. The request is based on November 1984 States' estimates and includes the impact of proposed regulatory and legislative savings of $1.1 billion.

These proposals are designed to maintain incentives for States to moderate program growth and improve the efficiency of program operations. Specifically, these proposals would limit Federal expenditures for medical assistance payments to $22.5 billion in 1986, while at the same time giving States greater flexibility to design and operate their medical assistance programs. A one-time hardship pool of $300 million would be available to assist States which, despite aggressive efforts to control costs, incur expenses above their limit. In addition, we are proposing to reform the current open-ended entitlement for State administrative costs and establish a separate grant which would be funded at the 1985 level of $1.2 billion. Similar reforms would be made for AFDC and Food Stamp administration.

PAYMENTS TO HEALTH CARE TRUST FUNDS

A total of $19.7 billion is requested for the Payments to the Health Care Trust Funds appropriation, an increase of $0.9 billion above 1985. This account reflects certain general revenue payments to Medicare, the largest being the Federal share of premiums for individuals enrolled in the Medicare Supplementary Medical Insurance (SMI) program (Medicare Part B). The growth in the Federal payment for the Part B program is primarily a result of rising program costs. The appropriation request represents approximately 75 percent of total Part B program costs.

PROGRAM MANAGEMENT

The 1986 budget request includes $82 million in appropriations and $1,114 million in trust fund transfer authority to administer the Medicare and Medicaid programs. Highlights of the program management appropriation include:

o Medicare Contractors

A total of $920 million is requested, an increase of $2 million above 1985, reflecting our commitment to continue to improve the effectiveness and efficiency of the administration of the Medicare program. Approximately 74 percent of the budget request

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for the Medicare Contractors, or $680 million, is allocated to claims-processing services. The remainder of the request will be largely used to assess the quality and appropriateness of health services provided to beneficiaries.

o State Certification

The $50 million request, the same level as in 1985, supports survey coverage of approximately 65 percent of facilities participating in Medicare. This level will provide annual inspections of all skilled nursing facilities and hospices and reflects the Department's continuing commitment to protect the health and safety of Medicare beneficiaries.

o Administrative Costs

A total of $205 million is requested for Federal administrative costs. This request reflects our successful efforts to bring about administrative efficiencies in the operation of the Medicare and Medicaid programs. The 1986 request will support 3,800 FTEs, a reduction of 180 FTEs from 1985 accomplished through attrition. Also, the budget assumes a 5 percent Federal salary reduction.

o Research

A program level of $22 million is requested for the research and demonstration program in 1986. At this level, the program will target research activities on policy issues concerning future reforms of the Medicare and Medicaid programs. This level of funding will support implementation of Congressionally-mandated studies and Administration priorities.

SOCIAL SECURITY ADMINISTRATION

The fiscal year 1986 budget for the Social Security Administration's (SSA) income security programs for the aged, disabled and poor totals $224.5 billion in outlays financed through both trust funds and general fund appropriations. These programs, which constitute about 68 percent of HHS budget outlays, will provide benefits to almost 51 million people in 1986.

For programs subject to appropriations, we are requesting $18.4 billion for 1986, in addition to previously appropriated advances of $4.9 billion. Advances of $4.7 billion for the first quarter of 1987 are also requested. The appropriations request by program is as follows:

SUPPLEMENTAL SECURITY INCOME

The 1986 appropriations request for the Supplemental Security Income (SSI) program is $7.7 billion, in addition to a previously appropriated advance of $2.3 billion. For the first quarter of FY 1987, an advance appropriation of $2.3 billion is requested. Federal benefit payments under this program will provide assistance to an average of 3.7 million recipients each month.

The 1986 budget request includes a cost-of-living increase of 4.1 percent payable in January 1986 and a projected increase in the blind and disabled population.

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AID TO FAMILIES WITH DEPENDENT CHILDREN

An appropriation of $6.7 billion is requested for Assistance Payments (AFDC) in 1986, in addition to $2.1 billion previously provided as an advance appropriation. Also, $2.2 billion is requested in advance for the first quarter of 1987. These funds will provide assistance to an average of 3.7 million families each month.

To reduce administrative burden and give States greater flexibility, we are proposing a legislative reform of Federal funding for State and local administration and training whereby States would receive fixed grants, with fewer requirements, to fund these activities. As part of the Administration's effort to reduce the deficit, we are requesting that 1986 funding be held to the 1985 level of $928 million, but that this amount be increased in future years based on changes in the GNP deflator.

The request also includes several other legislative proposals which continue reforms previously made in this program. They are intended to ensure that assistance is provided only to those who are in need and who are not in a position to provide for themselves, and that strong work requirements exist for all able-bodied applicants and recipients. In 1986, all legislative proposals for the AFDC program are estimated to save $180 million in AFDC and an additional $260 million in the Medicaid program.

CHILD SUPPORT ENFORCEMENT

Vigorous implementation of changes made by the Child Support Enforcement Amendments of 1984 will continue to be a major priority for me and this Administration in 1986. The 1986 appropriations request for the Child Support Enforcement (CSE) program is $592 million including an advance appropriation of $160 million. We are also requesting an advance appropriation for the first quarter of 1987 of $170.8 million. We estimate that child support collections will have more than doubled since 1980, from almost $1.5 billion to over $2.9 billion in 1986.

LOW INCOME HOME ENERGY ASSISTANCE

The Low Income Home Energy Assistance program (LIHEAP) provides block grants to States, Indian tribes, and territories for assistance to low income households for heating and some cooling costs, weatherization, and energy crisis assistance.

The 1986 budget requests a $2.1 billion appropriation for LIHEAP, the same as the 1985 level. However, the Administration is proposing legislation which would change the source of financing for this program in 1986. This proposal would allow collections from oil overcharge litigation settlements--for which the overcharged customer cannot be identified and repaid--to be used to offset general revenues for LIHEAP, without reducing total funds available to States. In 1986, an estimated $809 million in oil overcharged collections will be available for LIHEAP, thereby decreasing to $1.3 billion the amount of general revenues necessary to finance LIHEAP at the program level of $2.1 billion.

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REFUGEE AND ENTRANT ASSISTANCE PROGRAM

The request for Refugee and Entrant programs totals $317 million in 1986, a decrease of $89 million below the 1985 level. This reduction reflects the lower and more stable refugee arrival rates of recent years and the improved ability of communities to accommodate this population. The request also incorporates a policy to strengthen the role of initial resettlement agencies in fostering refugee self-sufficiency through cooperative agreements with the Department of State and private sector support.

OTHER PROGRAMS

We are also requesting $1.0 billion for benefit payments to disabled coal miners with "black lung" disease, and $0.5 billion for Payments to Social Security Trust Funds, primarily for certain post-1956 military service credits.

LIMITATION ON ADMINISTRATIVE EXPENSES

The Limitation on Administrative Expenses appropriation provides resources for SSA to administer the Old Age and Survivors, and Disability Insurance programs, certain health insurance functions, and the Supplemental Security Income program.

For 1986, we are requesting authority to spend $3.9 billion, an increase of $135 million compared to 1985. Most of this increase is for the contingency reserve which rises from $50 million to $175 million. This will provide the flexibility to deal with the many uncertainties in 1986 associated with implementation of the Disability Benefits Reform Act of 1984 and management of SSA's staffing reduction plan.

The staffing reduction plan provides for phasing down current staff levels without a reduction-in-force by 1,689 full-time equivalents (FTE) in 1986 and by approximately 17,000 FTE employees over the six-year period, 1985-1990. These reductions are made possible by increased productivity and service to the public resulting from a number of systems and procedural changes related to SSA's systems modernization efforts and other management improvements. Current plans provide for retraining and relocation of employees as new automated procedures are installed.

OFFICE OF HUMAN DEVELOPMENT SERVICES
AND OFFICE OF COMMUNITY SERVICES

We are requesting $5.4 billion in appropriations for programs administered by these offices in 1986.

The budget continues the policies of this Administration to support social services and related programs which promote self-sufficiency among program recipients, while focusing Federal resources on the most effective and efficient programs. In sum, the OHDS and OCS budgets will increase funding for adoption assistance; maintain most other service programs at their 1985 levels; reduce funds in selected research, training, and discretionary areas; and eliminate funding for the Community Services Block Grant and the Work Incentives programs.

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BLOCK GRANTS

The 1986 budget request for the Social Services Block Grant is at the full authorization level of $2.7 billion. No funding is requested for the Community Services Block Grant. Instead, the Department proposes that States use other sources of funding, including the Social Services Block Grant, to support those Community Services activities which are of the highest priority and most effective.

HEAD START

A total of $1,075 million is requested for the Head Start program which provides comprehensive support services and early childhood development for poor and handicapped children up to age 5. This level will support services to over 448,000 children, the same number as in 1985, and an increase of approximately 73,000 since 1980. Of the total enrollment, at least 10 percent will be handicapped.

AGING PROGRAMS

The 1986 budget includes a total of $689 million for Aging programs.

Within this total, $669 million is requested for Title III activities, the same level as provided in 1985. These include supportive services and centers, the nutrition programs of congregate and home-delivered meals, and State agency administration.

The budget request also provides $7.5 million for grants to Indian Tribes, the same level as provided in 1985. This level will enable approximately 127 Indian Tribes to provide service programs for their elderly members.

DEVELOPMENTAL DISABILITIES

A total of $75 million is requested for activities to develop and expand services for persons with developmental disabilities. In 1986, these funds will provide continued support for the Administration's effort to increase private sector employment opportunities for developmentally disabled individuals.

FAMILY SOCIAL SERVICES

The 1986 budget requests a total of $741 million for programs to keep families together or to support other appropriate living arrangements when reunification of children and families is not possible. As part of the Administration's effort to reduce the deficit, the request includes legislation to hold the Foster Care program, in 1986 only, at its 1985 funding level of $485 million. The request also includes $200 million for Child Welfare Services, $4 million for Child Welfare Training, $42 million for Adoption Assistance, and a total of $10 million for Child Welfare Research and Demonstrations and Adoption Opportunities activities.

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WORK INCENTIVES

In 1986, no funds are requested for the Work Incentives (WIN) program because, as studies by the General Accounting Office have demonstrated, this program has not proven to be cost-effective. Instead, legislation is proposed requiring job search and alternative work activities under the AFDC program, while giving states flexibility in the design of their specific program.

DEPARTMENTAL MANAGEMENT

The 1986 budget also includes $190 million for activities under the Departmental Management heading, $23 million below the comparable 1985 appropriation. Departmental Management activities include the Office of the Secretary, the Office of Inspector General, the Office for Civil Rights and the Policy Research program.

For 1986, the budget proposes further staffing reductions in the Office of the Secretary (General Departmental Management) through management improvements, including the increased use of automation. An employment decrease of 90 full-time equivalent (FTE) staff will be met through attrition under closely managed hiring and employment practices.

In our Office of Inspector General, we will target audit and investigative efforts on the large dollar programs which provide the greatest opportunity for fraud, waste, and abuse savings and recoveries. For 1986, we expect total recoveries, restitutions, fines, penalties and other savings will reach $4.0 billion, more than a tenfold increase since 1982.

The budget also carries out our obligations for civil rights enforcement and investigations. The $15.6 million appropriation request will allow the Office for Civil Rights to continue to emphasize voluntary compliance by recipients of Departmental funding. This approach has been very successful over the past few years, as evidenced by the fact that the number of new complaints received is stabilizing at just below 1,200.

For Policy Research, the budget includes $6 million, which will target research on health incentives projects, and will continue other activities that produce relevant information in a timely fashion.

Mr. Chairman, President Reagan's first term reversed the trend toward escalating costs which was jeopardizing the retirement income and health care of elderly Americans, impairing program discipline and effectiveness, and often producing unacceptable waste and fraud. The policies and programs put into place from 1981 through 1984 have succeeded.

Our goals for the next four years are no less important: finishing the task of securing health care benefits for this Nation's elderly, working with the States to provide quality health care for the poor in a cost-effective way, continuing this Nation's preeminence in biomedical research, and enhancing other services through more effective and efficient program management.

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When the history of our second term is written, it is our fervent hope and foremost objective to be able to say that, on our watch, American social policy has gained the high ground in achieving socially responsible and cost-effective policies which have enhanced our family life, helped the needy, and promoted a new self-sufficiency among our people.

That concludes my remarks, Mr. Chairman, and I would be happy to answer your questions at this time.

SECRETARY HECKLER'S SUMMARY STATEMENT

Secretary HECKLER. Thank you, Mr. Chairman, members of the subcommittee. Next month on April 19, in Boston and in the celebrated Middlesex towns of Longfellow's famous poem, there will be a reenactment of Paul Revere's famous ride. In 1775, Revere had only a cadre of supporters as he spread his historic alarm from Boston to Concord and Lexington.

Today, more than two centuries later, an equally important warning is being sounded—this time from east to west coast, northern to southern border.

The difference between 1775 and 1985 is that this year there is almost universal agreement about the danger which confronts us—Democrats and Republicans—economists and advocacy groups are united in recognizing the danger which the multiplying national deficit poses to our future security and prosperity. I appear before you this morning, Mr. Chairman, with an attempt to add my voice to that chorus while addressing the very serious needs of my department. The deficit danger is present, and it is clear.

The fiscal year 1986 budget for the Department of Health and Human Services, which I present to this subcommittee this morning, was drafted with that deficit danger in mind. We have tried in this budget to respond both to the needs of the millions of Americans we serve and the needs of our country's future. That is not an easy balance to strike. Many of our decisions have been wrenching ones.

It is always easy to say yes. Only when the time comes to say no does budget draftsmanship and budget enactment become painful and difficult.

You, Mr. Chairman, and your colleagues on this subcommittee have down through the years been our partners and allies in binding up national health and welfare wounds. You have been caring and compassionate. Your leadership and deliberations have helped to move this country and its people toward ever higher health and human services achievements.

I do not appear before you this morning to ask you to abandon that leadership or commitment. I do ask you to work with the administration in framing a Health and Human Services budget which responds to the deficit crisis so we can properly continue to serve the American people. We have a recent, wonderful precedent going for us.

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During the past 2 years, we have worked together in a unified, bipartisan effort to guarantee the stability of the Social Security system. We succeeded in that effort. You on this subcommittee and your colleagues in Congress deserve much of the credit for it. I believe we can, in working together on this 1986 budget, duplicate that success if we recognize the urgent need to reduce the Federal deficit on the one hand, even as we protect the needy and advance the overall goals of the people's department.

In the past 4 years, because of better management, innovation and increases in spending, the Department of Health and Human Services now manages to serve more Americans better than ever before in our history.

This week, I will transmit to the President and the Congress and release to the American people an important health report card, "Health United States, 1984." The statistics in that report are almost uniformly of honor roll quality.

Our national trend lines continue to move in the right direction in almost all categories. Deaths for the victims of strokes and heart disease are down. Infant mortality continues its decrease, while at the other end of the age spectrum longevity for all Americans records new gains. We Americans are living longer, healthier lives.

You in the Congress, we in the administration, and most of all, a more alert, sophisticated and health conscious American public can share in the credit for these advances.

Another facet, another front of the war against disease should be alluded to—immunization against childhood diseases has long been a priority of public health efforts in this country. I am proud to report record high levels of vaccination of school children and a record low rate of those diseases as a result. Measles, mumps, diptheria, chicken pox, whooping cough, and other childhood maladies have become almost medical relics in our country. Only brief and rare flareups of those diseases remind us of the national, killing epidemics of the past.

This 1986 budget is designed to guarantee a continuation of that kind of progress.

HHS will spend a total of $330.3 billion in 1986, including outlays from the Social Security and Medicare trust funds, as well as from Federal funds appropriated by the Congress. For the Department's programs considered by this subcommittee, our appropriations request for 1986 totals $79.7 billion.

I ask you to consider our submission in light of what has happened over the past 4 years. The President's economic policies which Congress put onto the statute books only 3½ years ago have reduced taxes, cut inflation, stimulated growth, and restored the economic health of the Nation. Ronald Reagan's overwhelming victory last year shows that the American people understood and were grateful for what he has accomplished.

As the President begins his second term, we want to continue the policies that have worked so well, address and solve the problems that

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remain and, at the same time fulfill our proper role and responsibility to the millions we serve.

The budget I submit today is based on three equally important assumptions:

First, spending increases must be reasonable in light of an ever-mounting Federal deficit.

Second, essential benefits for the Nation's most fragile individuals and families—the poor, the elderly, the disabled—are as critically important as ever.

Third, within the limits imposed by the first two assumptions, we must continue to make progress toward the general goals of the Department in both health and human services.

Each of these assumptions deserves discussion. There is a broad, national consensus that reducing the deficit is the most important national domestic problem we face. Unless the Congress and the administration act decisively now, the deficit will be $230 billion in 1986. That deficit would threaten us with higher interest rates, inflation and recession. As we painfully learned in the 1970's, none of us—rich, poor, or middle class—are better off when those economic conditions are rising.

Matching critical spending choices for services to the American people with their own capacity to afford the necessary taxes now and in the future is not an easy task. This is, however, the stuff of government. The time has come for us to make tough choices, to make them reasonably, to make them fairly, but to make them now.

In making those budgetary decisions, I am committed, as I know you are, to our ongoing special responsibilities to the poor, the handicapped, the ailing and the aged in our society—to all those Americans who are least able to fend for themselves. The President continues to stand with us on the side of those who, through no fault of their own, need our help. This budget tries to protect these Americans.

Of course, many of the programs administered by the Department of Health and Human Services apply not just to the needy but to millions and even tens of millions of average Americans.

Social Security is the program that personally touches more lives than any other. It is a major concern of those whom you serve. In 1981, the President inherited a Social Security calamity—the trust fund faced bankruptcy. Now, less than 4 years later, the Social Security Administration has just repaid $4.4 billion of loans it was forced to float from the hospital insurance trust fund and the disability insurance trust fund, and there is even better news for Social Security. In fiscal year 1986, the old age and survivors insurance fund will collect $7.6 billion more than it expends. That reverses a dangerous draining trend and it bodes very well indeed for the future financial solvency of the trust fund.

I am particularly proud of the fact that one of my earliest priorities as Secretary of Health and Human Services—putting the Social Security disability system back on track—is now well underway. Our screening and monitoring procedures have been simplified and clarified. They are more sensitive. They serve a very vulnerable constituency more fairly and more efficiently than before.

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The salvation of Social Security has been partnered by a second historic accomplishment—the growth of medical inflation has finally been reduced.

For the first time in many years, the rate of increase in hospital costs, and health costs in general, has fallen, and every indication is that the trend will be a lasting one. Our new prospective payment system and other innovative changes in health care financing which we have put in place with the Congress' assistance are responsible for much of that improvement. These reforms have fundamentally altered the behavior of patients, providers and payers regarding the use of health services. Productivity gains are being recorded almost across the board.

This achievement, again, was the product of partnership. Congress gave us statutory tools. We have used them with skill, determination and, I believe, fairness. We have also adopted a careful watchdog system, with bite, to ensure that quality of care and treatment are not compromised. We are in the process of proving that cost effectiveness is the ally, not the antithesis, of caring.

In this budget, major programs of the Alcohol, Drug Abuse, and Mental Health Administration and the Centers for Disease Control are funded at 1985 levels, as are the health block grants.

Biomedical research constitutes a total of about one-third of all discretionary expenditures under HHS. Funded at more than $4.8 billion in 1986, the National Institutes of Health will remain the world's premier biomedical research institution. Americans will continue to reap the health dividends of its vigorous, vital and pioneering research programs.

Let me cite another example of focusing our resources where they are most needed while simultaneously encouraging new, innovative ways of responding to problems—the Medicaid Program.

In this budget, Medicaid expenditures rise from $23 billion in 1985 to $23.7 billion in 1986. By limiting Federal contributions, while still allowing for growth to keep up with medical inflation in future years, we and the taxpayers will achieve major savings.

Many States have already adopted systematic reforms in the organization, financing and delivery of Medicaid services, largely as a result of our willingness to grant the States greater flexibility in managing their programs. Mr. Justice Louis Brandeis once and rightly called the States the laboratories of democracy. We embrace Brandeis' thesis—innovation and experimentation by the States is the best way to stretch the frontiers of quality medical care for the American people.

For that reason, recent Federal law has permitted increased program flexibility and new opportunities for substituting care at home for institutional care. The States have responded by organizing their programs in a more cost-effective manner. We have encouraged more emphasis on primary care, case management networks, and health maintenance organizations [HMO's].

Moreover, several States have replaced their traditional retrospective, cost-based hospital reimbursement systems for Medicaid with new pros-

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pective payment systems. Partly as a result of these new State initiatives, we have witnessed in recent years the most dramatic reductions in the rate of increase in Medicaid payments since the program began.

Another clear and effective example of our willingness to look at old problems in new ways is our effort to provide job-search and work opportunities for AFDC recipients.

For too long, our welfare system has focused only on meeting the family's basic bread and butter needs. That should be where the task really begins. Once those needs have been met, it is the responsibility of the welfare system to encourage and promote self-support. We believe our work opportunities proposal is the best approach for eliminating dependency, reducing poverty and helping families get back on their feet.

We are committed to the creation of work opportunities for AFDC families. The most effective means of reducing poverty is in assisting welfare recipients to move into the world of work. Through options such as job search, community work experience, and other work activities, our proposal will give recipients the skills and experience they need to become self-supporting.

We believe that, as working members of society, they will acquire a sense of dignity, self-worth, and confidence that no amount of welfare can provide. Equally important, the example of a self-supporting adult is a very important role model for children and helps strengthen family life.

Experiences in the 37 States now operating these programs have been enormously positive, both from a social policy perspective as well as the individual recipient's view.

Anywhere from 20 to 45 percent of the participants in the jobs program under welfare are finding unsubsidized employment. The great majority of supervisors and recipients continue to voice strong support for the programs because the work experience is meaningful and often results in securing a long-term job.

The Congregate and Home-Delivered Meals Program has become a model of public sector/private sector partnership as a result of the voluntary contributions from those who could afford to contribute and who we have encouraged to contribute.

Last year, more than $113 million was donated to these programs. That allowed us to serve more meals than ever before to needy people and to do all that without increasing the cost to the American taxpayer.

Our budget assumes that we will be serving 218 million meals in 1986, 3 million more than in fiscal year 1985. Our ability to increase the number of meals served while still remaining within the budget guidelines is made possible by the better management of Federal funds, including the increased program income I just referred to.

These management initiatives, first instituted in 1982, have been very successful. In fiscal year 1984 alone, we estimate that we have been able to serve 15 million more meals because of these improvements.

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You in the Congress showed your own openness to new ideas by the bipartisan support you enthusiastically gave the new Child Support Enforcement Program last year. Child support collections will reach $2.9 billion in 1986, almost double the 1980 level of $1.5 billion. And nearly all of that extra money will go directly to help families that truly need it. In many cases, it will actually lift poor families above the poverty level and off the welfare rolls.

Adoption assistance payments, which are used for the permanent placement of children in caring families, will be increased to $42 million. Support for low-income children and the elderly through other programs, such as Head Start and Aging Nutrition and Social Services, will be continued at the 1985 levels.

Some 200 years ago, Paul Revere's warning helped to mobilize a revolution that has brought one blessing after another to this Nation through a common commitment to sacrifice and sharing for the good of all.

It is my fervent hope and determination that we in 1985 will meet the challenge of the present, persistent deficit warning with the same sense of sacrifice and sharing.

The budget that I present to you, Mr. Chairman and members of the subcommittee, is in that spirit.

This concludes my remarks, and I thank you for your time and patience. I will be very happy to respond to any questions.

Senator WEICKER. I would hope Paul Revere's horse can make it over to the Defense Subcommittee of Appropriations if, indeed, there is this great call for sacrifice, since those who can best afford to make the sacrifice should make it.

I also have to say, quite frankly, without any meaning to insult the intelligence of the administration and yourself, that I will politely decline the honor of being a partner with the administration insofar as health, education, and the requests that have occurred over the years because, indeed, I think the record should be clear on this, at least insofar as the Senate Appropriations Committee is concerned. It has been one long, protracted struggle with the administration, both to maintain funding in certain areas, to increase funding in other areas and only by playing political hard ball, indeed, has this individual budget been protected and, in some cases, enhanced.

Whatever claims by the administration, and I am sure they can make many claims as to defense, inflation, these things they have every right to claim credit for. Insofar as the budgets of education, health, science, et cetera, I think the Congress has every right to claim the credit for staving off the worst of the proposals of the administration, but these are matters that we will get to as we go over the budget item by item.

Madam Secretary, you are aware that Congress appropriated $5.1 billion for this year, or $583 million over the President's request, and directed the department to fund 6,500 new and continuing research grants. Yet, you are now planning to fund only 5,000 grants this year. We are talking about fiscal year 1985.

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Do you intend to submit a rescission request to Congress for this reduction in grant awards?

Secretary HECKLER. No; we do not, Mr. Chairman.

Senator WEICKER. Why not?

Secretary HECKLER. As you know, Mr. Chairman, the funding for NIH research established in the appropriation bill envisioned both a number of grants and an economy that, shortly after the signing of the bill, turned out to have a less-promising outlook than had been anticipated.

Just after the signing of the NIH appropriation, the economy showed a slowdown in its GNP. In that very quarter, there was an indication that the deficit would be $20 billion higher than what had been anticipated. Suddenly, the mood of belt tightening became an overpowering motivation as we and all the other departments prepared our budgets.

I have to say that basic biomedical research is simply one of the areas in which I have the keenest interest and for which I have the strongest, most ardent support. Looking at the need to adopt an equitable policy and, at the same time, looking at the ramifications of a policy which would fund 6,500 grants in one year and then subject them to a freeze the following year, we felt NIH would be denied what I consider the most essential element of its future—the creation and preservation of a stable base of new and continuing grants.

One of the issues that faced me as a new Secretary was the need to confront OMB on the question of the 5,000 new grants. I insisted that 5,000 new and competing grants be funded, and that this level be a floor for NIH funding.

If we were to award 6,526 new grants for 1985 and 1986, we would have to add to the budget $538 million: $307 for continuation costs and $221 million to raise the 1986 level to the 6,526 grants. This would have put downward pressure on the subsequent year of grants. Our only alternative in a freeze posture would be in the subsequent year to reduce new and competing grants, to under 4,000 or to make offsetting reductions in other research mechanisms.

These were unacceptable answers. We looked for a means of dealing with what was probably this Department's most difficult dilemma in the budget. The concept of using funds for the obligated purposes by forward funding through the 2 subsequent years was the only answer that provided the continuation of 5,000 new and competing grants and a sense of stability and equity for NIH—not only this year, but in the future.

In that regard, it was felt by the general counsel at HHS and the general counsel at OMB that this is within the statutory authority of the Department and, therefore, no rescission would be needed.

Senator WEICKER. Therefore, you cite as your authority OMB insofar as this multiyear funding of NIH grants; is that correct?

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Secretary HECKLER. No; the general counsel of HHS and the general counsel of OMB.

Senator WEICKER. May I have a copy of your counsel's opinion concluding that multiyear funding is legal prior to any multiyear awards being made?

Secretary HECKLER. I don't believe it is reduced to writing. I am sure our general counsel will be glad to do that.

[CLERK'S NOTE.—The opinion was never received by the subcommittee.]

Senator WEICKER. Are you aware, Madam Secretary, that when the Department proposed multiyear funding in 1974 Congress pointed out that this was a violation of both the will of Congress and of the law and the Department, thereupon, ceased all attempts to multiyear funding of grants?

Secretary HECKLER. No; I'm not.

Senator WEICKER. Do we have your assurance that multiyear funding of NIH grants will not take place until July 1?

Secretary HECKLER. Yes; as I so expressed my point of view to the House Appropriations subcommittee.

Senator WEICKER. What you are indicating to me then insofar as this particular cut is concerned is that the cut was for purposes of budget balancing rather than the actual health needs of the Nation or the particular recommendations of NIH; is that correct?

Secretary HECKLER. No, sir; there were no countervailing forces from NIH during the consideration of this issue. The decisions were made based not only on budgetary factors, but truly on the need and desire to protect a stable base for NIH in the following years.

Senator WEICKER. As I recall your testimony just a few minutes ago, it was that the economic climate changed, the economic climate changed and we had a downturn in the economy; therefore, we then went to this particular area. That is the way I heard you testify.

Secretary HECKLER. Well, my statement related to one factor, which was the issue of the change in the number of grants.

Senator WEICKER. You people signed this law, didn't you? You agreed to this matter of 6,500.

Secretary HECKLER. Yes; the President signed the appropriations bill.

Senator WEICKER. And as you well know, these are always very delicate negotiations back and forth—you get some; we get some. This is the figure agreed to; am I correct?

Secretary HECKLER. Yes.

Senator WEICKER. And it is in the law?

Secretary HECKLER. That is true, although the actual levels are in report language.

Senator WEICKER. And there is certainly no mention of multiyear funding.

Secretary HECKLER. No; that is true.

Senator WEICKER. And the direction is very clear as to what is supposed to be entailed. As I said, I just want to know for the record, is

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this for budget reasons, insofar as the substance of the arguments, we agreed to that, you agreed; in other words, what you are saying to me, it is for budget reasons we have done this.

Secretary HECKLER. Our policy is based on budgetary considerations and the overall need to look at protecting the basic biomedical research base so as not to reduce the number of new and competing grants next year to over benefit grantees this year.

Senator WEICKER. How do you know it is going to be reduced next year?

Secretary HECKLER. Obviously, there will be a budget deficit of $230 billion without action to reduce it in very substantial ways, I think——

Senator WEICKER [interposing]. Madam Secretary, let's get one thing for purposes of this hearing clear, if you want to reduce the budget deficit, you do it in three ways—you reduce defense spending; that is where the dollars are; raise taxes and reform. This isn't going to affect the budget at all. Indeed, as we get into other programs where the tough choices are being made by the tough, and well off to the detriment of the weak—you make the tough choices.

I wish you could sit here with me as these weeks roll on, and I have people come before me who are going to be the recipient of these tough choices. I do not accept, as I said--you are here to go ahead and put forth the case, in fact, in many instances for the weakest elements of our society. Not the administration; not David Stockman, but those who are being served. I just want everybody to know that apparently in this particular instance, this is a choice made so far as cutting the budget that is going to impact in the out years as to what is available in the way of all these health breakthroughs, which your administration wants to claim credit for whenever they occur, but which you refuse to go ahead and fund.

In 1986—let's just continue on this track—the administration proposes—let's see if you can do as well as Weinberger—in 1986, the administration proposes to spend $58 billion Governmentwide on research and development—$58 billion. Of this amount, 68 percent, $40 billion, is for military purposes and 8 percent, $4.8 billion is for health.

Now, would you like to make a statement as to that 8 to 1 imbalance in favor of defense so far as your agency is concerned?

Secretary HECKLER. As you know, Mr. Chairman, there will be interaction between the Congress and the President, and the Congress and the executive branch. The priorities that are set in the budget are priorities that the President has established. These are his priorities.

Senator WEICKER. And they are yours, too.

Secretary HECKLER. Absolutely. In serving him, I carry his portfolio. This Department will spend $330 billion—$330 billion—this year, we are dealing with a Department that consumes the lion's share of the Federal budget. Although defense is increasing in size and scope, it is still behind this Department in spending by about $35 billion.

In addition to that, in looking at the hard budget choices, the fights that I made were on preserving the safety net programs that are essen-

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tial for those who are truly needy. In that regard, the President was supportive.

Now, I would like to have——

HHS DISCRETIONARY SPENDING

Senator WEICKER [interposing]. Staff can correct me if I am wrong, discretionary spending, where are we? $33 billion. What is the defense request this year? Two hundred and what?

Mr. DOYLE. $209 billion.

Senator WEICKER. $209 billion, somewhere around there.

Secretary HECKLER. Our outlays are $330.3 billion.

Senator WEICKER. I am talking about discretionary spending not entitlements.

Secretary HECKLER. I am talking about outlays for HHS for all programs.

Senator WEICKER. You know as well as I do that is not an indication as to what is going on around here. That is Social Security, Medicare, and Medicaid. It is not the programs we are talking about. We are at $33 billion, that is our discretionary end, discretionary end of defense is about $209 billion. Why don't you say that. Why are you trying to give a wrong impression?

Secretary HECKLER. I feel it is important to think of all the programs this Department funds. After all, the outlays go from this Department to meet the needs of Americans. And that is the role of the Department.

So, yes, the discretionary figures you recited are accurate, but there are colossal entitlement outlays that are also benefiting people. These are people programs as well. They are part of my daily agenda.

Senator WEICKER. Safety net. I recall reading in the newspaper, and I think somebody put a question in here on it. Safety net, didn't I see about a week ago we had a report on hunger in the United States? As I recall, it painted a very bleak picture.

A group of leading physicians and public health officials have just published the results of an indepth investigation of hunger in America. This independent body estimates 20 million Americans suffer from hunger, and cites evidence that hunger continues to grow.

Why are you freezing elderly nutrition services at the fiscal 1985 level of $403.9 million, even though legislation enacted last fall raises the authorization to $448.5 million?

ELDERLY NUTRITION SERVICES

In light of that report, how do you think we are doing on the safety net?

Secretary HECKLER. We have not had an opportunity to review that report and analyze it, so I personally have not read it. I did read a newspaper commentary on it. In terms of meals for the elderly, through voluntary contributions we have raised $113 million in 1 year. We will serve 3 million more meals this year with the same amount of money.

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Part of the way that this is done is through both voluntary contributions and volunteers' time in the Congregate Meals Program. It has attracted a very high level of senior citizen volunteers.

Frankly, we are stretching the dollar, which we aim to do instead of cutting funding. We are trying to freeze spending for programs. This is preferable to the elimination of programs that other agencies have felt in certain program areas.

We have proposed a freeze in most of our programs. In light of the overall deficit and the economic threat it poses to the country, this is an equitable policy.

Senator WEICKER. Freeze sounds pretty good until all of a sudden you ask the other question as to whether or not the population to be served is also frozen or declining. In most instances, I believe, it is not; it is on the increase, therefore, a freeze is really a cutback; isn't it?

Secretary HECKLER. Unless the dollars can be extended in another way. And there are ways to extend dollars, such as in the Congregate Meals Program, the voluntary contributions——

Senator WEICKER [interposing]. The report entitled, "Hunger in America: The Growing Epidemic," which was just recently published, headed by Larry Brown, chairman of the Harvard School of Public Health. The credentials seem to be quite in order.

Secretary HECKLER. Yes.

AFDC PROGRAM

Senator WEICKER. Some 20 million Americans suffer from hunger. I have already indicated your freezing elderly nutrition service at the fiscal 1985 level, even though Congress enacted legislation raising it to $448 million. Instead of expanding AFDC assistance as recommended by this report, why are you submitting legislative proposals to cut another $180 million?

You also are proposing to abolish Community Services Block Grant, which provides $335 million to local antipoverty agencies, supporting a variety of food and nutrition services.

I don't think all that jibes with the report on hunger in America and the fact your safety net has taken care of the poor and elderly and disabled.

Secretary HECKLER. Our proposed AFDC Program reductions largely relate to the creation of the work opportunities proposals. I think it is time to take a new look at some of the programs and some of the approaches that we have taken in the past. We need to recognize changes in our society, fortuitous changes.

All of the anecdotal material we have collected in the Department indicate that community work experience opportunities are truly changing the lives of many people who were totally welfare dependent.

It has reached the point where programs have been implemented in over 35 States, people are becoming self-sufficient through the work opportunities that they have found, and permanent jobs have been the result.

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Senator WEICKER. This must be why the administration, even though this isn't in your department, we just went through it, this must be why the administration is eliminating the Job Corps Program; is that right?

Secretary HECKLER. I can't respond to that. The administration is proposing to eliminate the WIN Program because, frankly, it is just a paper-passing exercise.

On the other hand, our work programs are proving to be very effective in enabling individuals to prepare for and find jobs. Frankly, they are very promising, in terms of potential savings for the Government, but even more importantly for the people involved.

Participants acquire a great sense of self-esteem by going out to work and doing something worthwhile. These are not make-work jobs, but lead to genuine employment opportunities. The reports I have had about self-esteem and the new attitudes that former welfare recipients have acquired through this work experience lead me to believe that we absolutely should mandate this as a State experience across the country.

We anticipate that under the proposed system—which is permissive in terms of utilization of work activities—that 89,000 families will leave or avoid welfare.

Thirty-seven States have implemented one or more work options. The best known, the Community Work Experience Program [CWEP], is operating in one-fifth of the counties, and its results are impressive. About one-half the States are operating CWEP programs with between 22,000 and 25,000 AFDC participants performing real jobs—school and hospital aides, library assistants, law enforcement work. It has really brought about the most upbeat, progressive, innovative changes that I have seen in the welfare system. Frankly, it is so promising that I think it should be extended.

Senator WEICKER. May I see a copy of the report on which your figures are based? Do you have a report?

Secretary HECKLER. There is no Department report, but we can send you a copy of the anecdotal and other evidence.

Senator WEICKER. What is anecdotal evidence?

Secretary HECKLER. Comments from the States and comments from individuals. State and local AFDC Program managers have sent in letters containing these comments. We can give you a collection of those comments. Also, the public newspapers have run interviews with individuals who have been on welfare and who have had the experience of participating in these programs and I am amazed at the success we see in the change of their own attitudes. It is so beneficial to the recipient. I think it is the most important breakthrough that we have seen in resolving the problems of welfare dependency.

[The information follows:]

As I stated earlier, my Department has not developed a formal report summarizing the results of our CWEP and job search programs. However, I am providing you with copies of four reports—on Washington's applicant job search demonstration project, "WIN Job Finding Clubs, San Diego's Job Search and CWEP Demonstrations and West Virginia's CWEP Program"—which support my testimony. The results of these

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studies, and preliminary results from a number of other States, including Maryland, North Carolina, and a Washington CWEP demonstration, show that:

One, CWEP and job search programs can improve the employment prospects of welfare recipients and reduce welfare dependency. For example, in the San Diego project, first quarter earnings of welfare mothers participating in these programs were 28 to 36 percent higher than earnings for nonparticipants. Welfare expenditures were reduced 7 percent for the regular AFDC caseload and 14 percent for the AFDC-UP caseload. From all the research we've seen, work programs provide particularly effective in improving the employability of welfare mothers with poor education or employment records or a long history of welfare dependency.

Two, CWEP and other work programs can be implemented with few, if any, major implementation problems and can serve a substantial portion of the welfare caseload.

Three, these programs enjoy strong positive support from the public, participants, program administrators, and supervisors. For example, a number of surveys have shown that 90 percent of the public support programs like CWEP. They serve to enhance the image of the welfare system and of welfare recipients.

The figures on participation levels come from an informal survey we conducted more than 1 year ago. The figures were similar to, but slightly lower than, figures compiled by the National Governors Association and published in the report, "Work Programs for Welfare Recipients—Issues and Options." NGA estimated 38,770 participants in CWEP-type programs; however, its figures include food stamp, refuge assistance, and general assistance recipients also.

I have also provided just a sample of some of the news articles and statements we have received testifying to the potential benefits of CWEP and job search programs.

[CLERK'S NOTE.—Additional material submitted by the Department is in the subcommittee's files.]

MINORITY UNEMPLOYMENT RATES

Senator WEICKER. Is it correct then to extrapolate from that independent hallelujah from the administration that the unemployment rates for blacks, Hispanics, young people are coming way down?

Secretary HECKLER. I would say so. However, it is not now a mandatory program for States, and it is only operating in 37 States, and not universally or statewide in all of those States. The upbeat nature of the economy itself has increased employment opportunities across the board, and to assist welfare recipients to be a part of this is really a very promising experience.

HUNGER IN AMERICA

Senator WEICKER. I want to read you some of the excerpts from "Hunger in America," and then I will turn the questioning over to Senator Proxmire. These are excerpts.

Hunger in America is a national health epidemic. Hunger in the United States is now more widespread and serious than at any time in the last 10 to 15 years.

The number of poor Americans increased by more than 9 million in the last 4 years—the largest increase since poverty figures began being compiled in 1960.

Economic hardship rose to a level unparalleled since the Great Depression • • • The increased need was largely ignored, and safety net programs were actually cut even as hardship grew.

Among the most vulnerable children, those under the age of 6, 1 in 5 lives in poverty.

Neither food stamps nor AFDC, nor both together, provide American families with the level of support required to eat nutritiously and to maintain health.

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AFDC benefit income for families in the Nation decreased by 33 percent between 1970 and 1984.

Approximately one-quarter of the States provide no Medicaid coverage for medically needy families.

This is somewhat a different view of the United States than that which you have given me. Would you like to explain what the discrepancy is?

Secretary HECKLER. I think perhaps one point should be raised. Almost two-thirds of the increase in poverty since 1979 occurred between 1979 and 1981 before the President's program was implemented. Between 1979 and 1980, 12.2 percent more people were poor. From 1982 to 1983, the rate of increase had slowed to only 2.5 percent. The rate of increase of poverty has been stalled as the economy recovers. The numbers of poor are growing because of the population growth in this country. In fact, it is promising to see the growth rate experience such a tremendous decrease. When the overall population increase is taken into account, there was no statistically significant increase in the poverty rate from 1982 to 1983.

Senator WEICKER. What do we do about these people? They are not a statistic; they are hungry; they are diseased; they are hurting. What do we do about them? I don't care if the rate is slowed down. They are out there. What are you going to do about it, what about the program?

Secretary HECKLER. No; I think the Food Stamp Program is very good. At the same time, I think you know as well as I that the Food Stamp Program does not require an especially nutritious diet. Hunger in America has to be somewhat related to our food consumption habits at all levels of our society, and while we offer food stamp benefits, we do not ensure a nutritious meal or menu for the food stamp recipient; one can eat and still have a nutritional deficiency. That, I think, is going to be the case until we follow Senator Proxmire's advice and change our eating habits.

Senator WEICKER. Very simple, all you have to do is issue a press release and tell them how to eat. Won't cost anybody a nickle around here.

Secretary HECKLER [nodding to Senator Proxmire]. He has written a book about it.

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Thank you, Mr. Chairman. Madam Secretary, I want to congratulate you on your statement and your heroic defense of the administration's position. I think you are a fine secretary, and I admire you very much. But let me ask you about your comparison of the Health and Human Services budget with the Defense budget.

I think if you include all of the defense expenditures of this country, not just the Defense Department's budget, but, for instance, the budget for nuclear warheads funded by the Energy Department and military foreign aid, which is, of course, outside the Defense Department's budget, total defense expenditures come to $320 billion or something like that.

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Of course, the Social Security portion of your budget, which is by far the biggest part, is based on a dedicated tax: it is a transfer payment program, as you know, and it is supported entirely by the Social Security tax, which simply transfers the funds from your working contribution to benefit payments when you retire. This leads me into the question I want to ask you.

On page 7 of your statement you indicate that in fiscal year 1986 Old Age and Survivors Insurance will collect $7.6 billion more than it expends. Fiscal year 1986 is the year beginning on October 1, 1985. The President's position is that we should not reduce the cost-of-living adjustment [COLA] for people on Social Security. The chairman of the Senate Budget Committee proposed that we freeze that COLA and not provide a COLA in 1986.

It is hard for me to understand the basis of that proposal, although, of course, I favor holding down spending in any way I can. The proposal seems to me unfair in the sense that you have a dedicated tax which is in surplus. All you would do in knocking out the adjustment is to increase the surplus in that account which, obviously, can't be used to pay for military spending, for environmental protection or for education costs. The Social Security trust fund is dedicated for one purpose.

SS COLA'S

So what sense does it make, what would it really contribute other than a bookkeeping gimmick, if we skipped the cost-of-living adjustment for 1986 for Social Security recipients?

Secretary HECKLER. I personally don't think we should skip the COLA in 1986. As you will recall, in 1983, when the Social Security amendments were passed, the COLA was delayed. So the Social Security recipients, many of whom are fairly poor, have already made a sacrifice.

Senator PROXMIRE. It was reported in the press that 500,000 people would be dropped into poverty if the cost-of-living adjustment is not made in 1986. Maybe that is an exaggeration, but a very large number of people would fall below the poverty line.

Secretary HECKLER. There are many elderly with low incomes. They have made a contribution; their COLA was delayed in 1983. I really believe we can afford to honor the President's commitment to the senior citizens, and I believe we should.

NIH RESEARCH GRANT AWARDS

Senator PROXMIRE. I want to get back to one of the areas the chairman discussed with you. On page 8 of your prepared testimony, you state that funding 5,000 new and competing research awards annually continues a policy of research stability supported by this and previous administrations. Maybe 5,000 awards is the right level. I am not going to argue that point at this time. But as a matter of statistical fact, if NIH awards 5,000 such grants in 1985, wouldn't you be implementing a cut of about 9 percent below last year's level of 5,493 awards?

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Secretary HECKLER. That is true.

Senator PROXMIRE. How does that provide stability?

Secretary HECKLER. One of the first issues I faced as a new Secretary of HHS was the level at which NIH grants should be funded. This was one of the unresolved questions between my predecessor, Mr. Schweiker, and OMB. I fought very hard to maintain the floor he had established, so that NIH would always be funded at 5,000 new and competing grants. This was our basic premise.

In 1984, in our budget submissions, we established a figure of 5,000 new and competing grants. Subsequently, the NIH Director found other funds, and so the funds supported roughly 5,400 grants. It did not go below the 5,000 level.

One of the difficult questions we faced last year in looking at the 6,525 grants was the question of how to continue those grants. If you fund 6,500, the anticipation is that the funding would continue for 3 years. To continue those grants for 3 years with a freeze policy, the general policy of the Government and the whole COLA mark of the budget in general except for certain exceptions that you know as well as I do, nonetheless, with a freeze policy, then we would have to in that second year of continuation, if we were to continue the new and competing grants funded in 1985, in 1986 we would have to cut back in some of the other grants.

What that would do, then, is throw into turmoil the continuation of earlier grants or necessitate a very steep level of increase in grant awards.

I would personally find that desirable in the best of all worlds. But with a deficit of $230 billion, it seemed to me stabilizing funding and honoring a floor of 5,000 grants—making that predictable without fluctuations below that level—and continuing that policy was the best way to protect the basic biomedical research.

Senator PROXMIRE. What is the difference in cost between your proposal and continued funding at the 1984 level? Can you give me just a rough notion of what we are talking about? Are we talking about $1 billion?

Secretary HECKLER. I think it would be less than $1 billion. Our request this year is $4.8 billion.

I am told it would be about $150 million.

Senator PROXMIRE. And that would be about 3 percent of this year's budget of $5.15 billion.

Secretary HECKLER. Yes.

Senator PROXMIRE. Your first round of 1985 awards assumed you would be funding 6,500 grants. If you cut back to 5,000 grants in 1985, aren't you funding the second and third rounds as though you were awarding less than 5,000 grants?

Secretary HECKLER. Yes; the notices from the first review cycle were sent out before recognition of the growing size of the deficit. It envisioned implementing the will of the Congress as it was expressed in the appropriations bill. After that, we had to curtail the amounts that we

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would fund. So to get back to the 5,000 level, we'll have to make adjustments in subsequent award amounts.

We have not made multiyear grants yet, because we are consulting with this committee and with the House Appropriations subcommittee on the subject. Obviously, this is going to take a long time to discuss and resolve.

Senator PROXMIRE. I want to congratulate you on the statement you made about the positive aspects of health trends during your term of office—the fact we have greatly improved longevity and made real progress in overcoming cancer as well as heart disease. It is very heartening. There have been complaints on my part, and I am certainly one of those leading the criticisms, on the cost of these programs, and yet they have done a marvelous job of providing healthier and happier lives for many people.

In that connection, as you know last November this subcommittee held a morning hearing on variations in medical practice patterns which considered, among other issues, the need for research into the outcome of various common surgical procedures. I am speaking of longitudinal studies that would follow patients for at least 1 year after their surgery to see how they did as compared with a group of patients who received drug therapy or some other kind of nonsurgical intervention. It is a way of trying to provide better health and saving a lot of money by reducing unnecessary surgery.

One of our witnesses explained that if low-cost patterns of care were the norm, including fewer surgical procedures, we would not be faced with a Medicare trust fund crisis. That is why outcome studies are so important. Medicare funds may be buying a great deal of unnecessary care, but without outcome studies, we just won't know what medical care is appropriate.

MEDICAL PRACTICE PATTERNS

One of the startling facts that was deduced at that hearing was that in Los Angeles they had a doctor's strike for a short time during which only emergency surgery was performed. No elective surgery was allowed. Deaths dropped dramatically, which was a startling revelation.

Can you tell us how much the Department plans to spend on outcome studies in fiscal years 1985 and 1986, and provide a list of 1984 outcome studies for the record?

Secretary HECKLER. I will be very happy to provide that for the record. I don't have an exact figure. I will say that we feel the peer review organizations, implemented as part of the prospective payment system, will review the quality of care. They will see whether or not procedures are necessary and provide responsible answers to the Department so that we may be sure we are containing costs and preserving quality.

Through that mechanism, we will probably have the best vehicle for gathering information on unnecessary surgery and on virtually all of the procedures, whether necessary or unnecessary.

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In addition to that, the National Center for Health Research performs health care technology assessments in support of Medicare coverage decisions relating to safety, effectiveness and acceptability of the new medical technologies. They have just recently completed a number of assessments in this field.

Senator PROXMIRE. The trouble is, Madam Secretary, without outcome studies, we won't know whether certain procedures are efficacious or not. You see, we have a situation where in one State, depending on what part of the State you live in, there can be a difference of 300 percent in the proportion of patients who receive surgery for prostate problems or hysterectomies and yet we have no outcome studies to determine whether those who receive less surgery do better or do worse. That is what we need.

Secretary HECKLER. Well, I think that is true, and I certainly will go back to the Department with your request for more specific information on outcome studies. I really would not underestimate the advantage of the peer review organizations. In reviewing admissions, they are mandated to ensure that medically necessary services are provided, are provided in the most appropriate setting, and are of the right quality to meet professional standards.

In the process, the system itself will develop a really credible body of outcome studies, which not only could assist HCFA, but certainly will also help the American people in their own medical decisions.

Senator PROXMIRE. On page 15 of your prepared testimony you refer to research activities on policy issues concerning future reforms of the Medicare and Medicaid Programs.

To date, the Health Care Financing Administration has spent $2.5 million to evaluate second surgical opinion programs. I am told that at a recent Brookings Institution conference one of HCFA's professionals cited a private sector second opinion program as one example of steps being taken outside the Government to control medical care costs.

Furthermore, requiring second opinions in the case of certain common elective procedures would give elderly recipients of Medicare a reason to ask for a second opinion and remove their fear of offending their physician by such a request.

I cannot for the life of me see why you do not make a mandatory second opinion requirement part of your legislative reform package, especially in view of the wide variations in many elective surgical procedure rates across the country. What is holding you back?

Secretary HECKLER. There have been a number of studies which would indicate second opinion programs may be cost effective. A number of third-party insurers and State Medicaid programs have adopted them.

However, we believe that the evidence of whether a program of this type would be cost effective for the Medicare population is inconclusive. We are concerned about the quality of care implications if surgery is delayed for the elderly. Rather than instituting a mandatory second opinion program at this time, the Department will rely on preadmission

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reviews, which PRO's are currently performing on a selected set of procedures. For example, cataract surgery, for which there is evidence that outpatient surgery or treatment may be more appropriate or more cost effective.

Senator PROXMIRE. My time is up. Let me just say I do hope you will reconsider a mandatory second opinion requirement because if it is mandatory, if doctors know a second opinion is mandatory, they are much more likely to be cautious in recommending surgery than if a second opinion is optional.

My dad was a doctor and my son-in-law is a doctor. I think it is a marvelous profession. But that is the way the doctor sells his care. It is like a used-car dealer selling a car. If you want to perform an operation you have to sell the patient on the need for surgery.

Secretary HECKLER. We certainly will take it under advisement.

Senator WEICKER. Thank you, Senator Proxmire. Let me continue, if I might, just for 1 minute on the grant situation so we might set the legislative record in proper perspective. One of the first matters that came across my attention was the cuts in the grants. We managed to keep it at the 5,000 level. The reason we went to 6,500 wasn't because this was some well-meaning gesture by Congress, rather it was to try to keep the percentages in proper order, vis-a-vis the percentage of applications funded, the number of applications approved.

In 1979 you had 11,510 applications, grant applications approved, and you had roughly 5,944 applications funded, which gave you a percentage of applications funded at 52 percent.

Now, as to the applications funded, let's see what the record is. In 1980, that percentage went to 42 percent; 39 percent in 1981; 35 percent in 1982; 37 percent in 1983; 37 percent in 1984; 31 percent in 1985.

What the Congress tried to go ahead and do by the 6,500 figure is bring this back up and get going in another direction. It was estimated if we have 6,500, then you are talking about roughly 40 percent of the applications being funded. If you hold at the figure we are talking about here, the estimate for 1986 indicates you will be going down to 29 percent as the percentage of applications funded.

So let's not be fooled by the dollars and the numbers. This is what is happening. The point I want to raise publicly is the matter of out-year costs. I am delighted my good friend, Senator Proxmire, appreciates what is occurring in the sense of the breakthroughs, vis-a-vis diseases, infirmity, et cetera. The fact is that those were funded long before this administration came into office. Indeed, long before the prior Democratic administration. This money has to be put into that pipeline if, indeed, it is going to show results 10, 12, 15 years out. That is the difficulty with what is going on here now.

Everybody says, "Hooray, we cut the grants; we cut the money." Nobody is going to feel the cost of that; nobody in this room this year, not even next year, but we will feel it down the line both as older people and certainly our children will feel it. That is what is involved.

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The Congress was very specific on the matter of this grant business, and I would hope the administration will do what it did back in 1984, reconsider its position and come to the level the Congress insisted on insofar as 1985 was concerned. That was, as I say, a carefully crafted agreement between the administration. It took into account all factors. The administration wasn't unmindful of the economics of that time. They are loaded with economists over there that can tell them what is going to happen next year and the year after that.

AIDS RESEARCH

Last year, you requested $54 million for AIDS research. Congress appropriated $96 million. If you do restrict NIH grants to 5,000 this year, how many fewer AIDS research grant awards will be made than if you maintain the overall 6,500 grant level?

Secretary HECKLER. I have no idea what level of research is devoted to AIDS versus all the other areas of disease investigation. As I have said, AIDS has been a priority. To have this disease continue at its current rate is a very serious public health crisis in the country. We have made substantial improvements, and we have had great breakthroughs in AIDS in just the 3 years since it was identified. This disease didn't exist before that time.

We have already identified the cause of the disease, the human cell virus HTLV-III, and we have just licensed a blood test which will be made available by other manufacturers. AIDS research is a necessary priority. The National Cancer Institute, however, and the National Institute for Allergy and Infectious Diseases have decreased their requirements for AIDS funding because of the decline in the number of requests for research support in this particular area. We are supporting very brilliant researchers in the field of AIDS, and we would not have been able to make the gains we already achieved were it not for the number of scientists already engaged in AIDS research. That will not be jeopardized. As I have said, I have told all the scientists at NIH, CDC, and FDA that their needs must be addressed and have to be brought to my attention quickly. I intend to support them and seek further financial support or an appropriation if the situation warrants it.

That has been my operating system ever since I identified AIDS as the No. 1 public health crisis in the country.

ALZHEIMER'S DISEASE

Senator WEICKER. During last year's hearing, you stated, "I think it is important that the Alzheimer's breakthrough be encouraged." The Assistant Secretary for Health states in his fiscal year 1986 budget justification, "As the U.S. population ages, the number of people affected by Alzheimer's disease is rising."

Well, this subcommittee, the full committee, Senate and House agreed with you and funding for five additional Alzheimer's research centers was enacted. You are proposing to fund only three new centers in fiscal year 1985; is that correct?

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Secretary HECKLER. That is true.

Senator WEICKER. Is this not another attempt to impound appropriated funds?

Secretary HECKLER. This is the application to research centers of the multiyear funding principle that we have discussed for grants. The research centers were in virtually the same situation as the grants in terms of continuation funding. So it was necessary to forward-fund research centers, and that did require a delay in implementating of our desire to have five centers added to the Alzheimer's research program.

Due to the freeze policy, three of these will be funded this year, and two in 1986. I would note that, in addition, five were funded in 1984.

THE TWELVE-MONTH GRANT AWARD RULE

Senator WEICKER. Let me read the language that was contained, alluded to earlier in the supplemental appropriations bill of 1984.

> In the past, the department has been careful to allow only a very few exceptions to the 12-month grant award rule. Even then the exceptions were made only with the prior approval and the consent of Congress. It appears to the committee that any attempt to provide multiyear grant funding, or forward funding, would be in direct opposition to the will of Congress and apparently a violation of the recent court rulings mandating the release of previously impounded funds.
>
> In summary, the committee again strongly reaffirms its position that all grant award must be made on a 12-month basis unless specifically provided to the contrary by the Congress. Unauthorized multiyear funding changes the intent of Congress without its consent. It destroys the annual appropriations process, reinstates unlawful impoundments, and usurps congressional prerogatives.

Has this become a matter of policy, this multiyear funding routine, in your department?

Secretary HECKLER. We are proposing the policy this year because of the special conditions that have existed and the circumstances that I have cited.

However, we have said that we will consult with you. Mr. Stockman has made the same statement to the House Appropriations Committee.

We feel, and our general counsel feels, that this appropriation approach is within our statutory authority. When an appropriation is made available, the general rule is that the availability relates to the authority to obligate funds and does not necessarily prohibit later payments; thus, we were restricted by the annual appropriation to make the grant award obligation within fiscal year 1985.

In the case of the grantees, performance will extend into the subsequent fiscal year. Since the actual grant obligation occurred in 1985, we do not need to rescind funds. NIH is obligating the entire amount appropriated, but allowing the grantees to spend these funds over 3 years.

A rescission of funds constitutes withdrawing spending authority and not permitting the appropriated funds to be spent. We have not withdrawn spending authority. We are simply spending it over a longer period.

We have also said that we will consult with the subcommittees in both the House and Senate.

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Senator WEICKER. It seems to me there are three ways around this problem. No. 1, we go to court. That seems to be a waste of taxpayers' money. No. 2, I suppose what we could do in the fiscal year 1985 bill, put in the moneys, in the case of the centers, for the requisite centers we mandate, or in the case of the grants for 6,500 and indicate in no set of circumstances can that money be forward funded in the sense of multiyear funding.

If you people agree to that, then that obviates that tactic which you are now using.

Alternatively, I have a proposal for you and I don't know what the outcome is going to be. I have laid this matter in the hands of the General Accounting Office to ask them their opinion as to the legality of what you are doing. Would you like to abide by their decision? I don't know what the decision will be. We understand in 2 or 3 weeks we should be getting an answer. Would you like to abide by that?

Secretary HECKLER. We have had good legal counsel look at this, and it is their opinion this is perfectly acceptable. I think the GAO is an excellent auditing arm of the Congress and valuable in that sense. I am not sure their legal interpretation is quite as sacrosanct as their auditing expertise. I don't think that is an appropriate——

Senator WEICKER [interposing]. Madam Secretary, you are the one trying to circumvent the law, not the Congress.

Secretary HECKLER. I didn't say the Congress was.

Senator WEICKER. This is clearly outside of what was agreed to in the last bill. You are the one who is changing the rules here. It seems to me you better have justification for that.

Secretary HECKLER. We feel we do intend to.

ALZHEIMER'S DISEASE

Senator WEICKER. Counsel indicates to me the Comptroller General in the Budget Act will be the one who will make the determination as to whether it is appropriate or not, but then you get to the point where last year you are the one who sat here, indeed, and I believe took credit for part of the breakthrough at that time, and it didn't turn out to be much of a breakthrough on Alzheimer's disease and indicated the importance of it, and here you are cutting back.

Secretary HECKLER. We are still funding——

Senator WEICKER [interposing]. Let me ask you a question. Are there fewer people this year, in the coming fiscal year, that are going to suffer from Alzheimer's than last year?

Secretary HECKLER. Sadly, our predictions are the number of victims is increasing.

Senator WEICKER. Sharply increasing; therefore, probably last year's number of centers is probably inadequate for the task at hand.

Secretary HECKLER. We are funding research, and we are funding demonstration projects with new technology such as imaging machines which allow us to identify very precisely, the Alzheimer's disease and cells in the brain.

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The research is becoming more sophisticated. It does offer hope, although no breakthrough has been made. Last year, we thought there was a breakthrough forthcoming, so our research is still aggressive. We have excellent people doing it. So many areas of research, not only Alzheimer's disease, are terribly important. I would never undermine that.

However, at a time when we face a $230 billion deficit——

Senator WEICKER [interposing]. Madam Secretary, when you have people suffering from Alzheimer's disease, don't use them as an excuse to balance the budget. Balance it some other way. I don't think you want your name on the record saying we have to balance the budget, therefore, *x* number of people who have Alzheimer's will be wiped out. That is not the way to balance the budget, either with them, or the retarded, the disabled. Balance it some other way. Don't stand up to bat and say this isn't worth paying for.

You are darn right, I am perfectly willing to pay whether it is my mom, dad, friends, eventually myself, I would like to feel I have done everything possible in this particular illness. There are millions of Americans suffering from different ailments. Why balance the budget on their pain? That is what I don't understand.

I am going to insist, I am going to absolutely insist when we have these public portions of these hearings and these people that have their various afflictions come as individuals, not as secretaries or under secretaries, directors of the budgets—I want someone from your office sitting up here with us to listen to what is going to be told. Maybe that will give you an idea as to why we get a little worked up on this committee when we see these kinds of cuts, cuts in Alzheimer's, in research grants.

SUPPORT FOR THE ELDERLY

It is estimated America's population of 75 and older—75 and older—will increase over 50 percent by the year 2000—50 percent. And that is the reason why in the last budget I proposed a new program, only $5 million, to start involving our universities in courses in geriatric care.

How many of you know in this room that out of 122 medical schools, only 2—only 2—offer courses preparing doctors to be specialists in the area of geriatrics? Only 2 out of 122. Here you have a statistic facing you right in the kisser, 50 percent increase in the 75 and older population by the year 2000; $5 million to start this on a pilot basis, and you propose to eliminate that in fiscal year 1986. What are we going to do for these older people, just out of curiosity? How are we going to have the type of care that clearly is going to be demanded by the public? Do you think we do that best when all of a sudden the problem hits us in the face in the year 2000 or we prepare ourselves for it? Which is money saving? My idea or postponing it?

Secretary HECKLER. I am sensitive to your concerns. When in Congress, I drafted a bill that provided for the geriatric centers of the veteran hospitals. And a great deal——

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Senator WEICKER [interposing]. I am talking about this program, which came out of this committee. You didn't draft it.

Secretary HECKLER. Not this one.

Senator WEICKER. The committee did.

Secretary HECKLER. I am saying——

Senator WEICKER [interposing]. Why is it cut in light of those statistics? Why is the program eliminated?

Secretary HECKLER. In light of——

Senator WEICKER [interposing]. The budget.

Secretary HECKLER. Yes.

Senator WEICKER. Even though the facts also show an increase in the elderly population of 50 percent by the year 2000?

Secretary HECKLER. Budgetary priorities have to be set with the most urgent needs. The priority in the aging community, for example, at our National Institute on Aging, enormous research is being done——

Senator WEICKER [interposing]. You know what this is to me? It is very simple, very simple. I will tell you the guiding philosophy of the administration as I see it coming through this budget. The old adage, survival of the fittest; survival of the fittest. God help the culls in our society.

Secretary HECKLER. Our survival is getting better.

INFANT MORTALITY

Senator WEICKER. No; it isn't. For example, I see great statistics on infant mortality in the United States. Good for that statistic. Do you want to know what the statistics are in infant mortality in the Nation's cities, which is where you have your concentration of the poor and the minorities, you know what those statistics are? They are ghastly, and they are on the increase.

This is 1978–80, the city of Hartford infant mortality rates per thousand live births, Silent Hill area, some of the poor areas of the city, 29.5; 29.2; 23.8 in upper Albany. With these statistics—great safety net.

Secretary HECKLER. These are not consistent statistics. In 1984 we had a report in Boston of very, very high infant mortality rates. The very next year, the same report showed a tremendous improvement, in fact, the highest gain in that program that Boston has ever achieved.

I think we have to target our resources to those people who are at high risk. In terms of infant mortality, one of the most important things to do is to make two things known to pregnant women: that smoking creates a very strong probability of low birth weight babies; and that the major problem with infant mortality is low birth weight.

In the Department, we have initiated programs, conducted conferences, studied the issue, had work groups——

Senator WEICKER [interposing]. Do you know what the main reason for infant mortality in these inner-city hospitals, Madam Secretary—at least as I understand it in testimony given before the committee—do you know the main reason cited by the doctors—New York, Boston—the first time they see the woman is when she comes into the hospital in labor.

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Secretary HECKLER. That's true.

Senator WEICKER. Because of the funding cutbacks that have occurred in these areas as far as care, maternal care.

Secretary HECKLER. We have implemented the law's requirement that pregnancy care, prenatal visits, be mandated for pregnant women under the Medicaid Program which we operate jointly with the States. We are insisting on prenatal care.

Since 1979, there has been a decrease in prenatal care among many, many women, black women especially, but women from all economic backgrounds and education levels. There is no explanation for that. An emphasis on prenatal care is entirely appropriate and this is something I strongly support.

Senator WEICKER. I know, but the funding doesn't indicate that. The funding hasn't indicated that for the last several years.

Secretary HECKLER. Problems with Medicaid funding are attributable in many aspects to State practices which do not encourage tapping outside resources. While the Medicaid Program is an element in our attempts to provide prenatal care for low-income women, the program itself does not inspire the States to use all alternative funding sources. The GAO has estimated that between $500 million and $1 billion is lost annually because States do not aggressively pursue third-party payers. And if they were to do that, we would be able to cut Government expenditures for Medicaid, which we are proposing in the budget.

MATERNAL AND CHILD HEALTH

Senator WEICKER. I am going to turn the next time over to my friend Senator Proxmire. You have proposed freezing the Maternal and Child Health Block Grant at $478 million, the same as the fiscal year 1985 appropriation. I want to know what services will have to be reduced due to inflation, and there is an inflation factor, increased costs and, obviously, increased population?

Secretary HECKLER. The freeze policy is, again, the equitable response, and I feel——

Senator WEICKER [interposing]. Equitable response to whom?

Secretary HECKLER. To a budget deficit that is a colossal problem to the country.

Senator WEICKER. To the pregnant woman, the mother?

Secretary HECKLER. Maternal and child health is one of our priorities. This is why it is frozen and not reduced.

Senator WEICKER. But it is reduced.

Secretary HECKLER. No.

Senator WEICKER. It is reduced by virtue of the increased population you are serving and increased costs.

Secretary HECKLER. All the mayors have asked for a freeze——

Senator WEICKER [interposing]. I am not a mayor; I am not asking for a freeze.

Secretary HECKLER. They are living on Main Street with the problems you cite. They deal with those problems each day.

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Senator WEICKER. I don't think they are living with them very well if they chalk off *x* number of pregnant women. I don't think that is what they are saying.

Secretary HECKLER. I think there has to be some room in all of our budgets for individual increases in productivity. This is one of the things that we are stressing in the Department: gains can be realized in this area. The Medicaid Program itself should be using third-party liability much more aggressively: $1 billion could be saved from Medicaid, which is what we are proposing this year.

Senator WEICKER. You know what you ought to be talking about saving? I notice in the "Children's Defense Fund" article that appeared in the Washington Post on February 28, they state, out of another 100,000 infant deaths in which low-birth weight was expected to be a factor although not necessarily the only one, 13,800 could be prevented if the mothers received early comprehensive prenatal care.

Secretary HECKLER. I agree.

Senator WEICKER. For all the Right to Life, Pro-Life, et cetera, like that, but 13,800—forget that, that is part of the budget balancing act.

Secretary HECKLER. No; we are saying this is a requirement of the law. We are mandating that the Medicaid Program include pregnancy prenatal visits in every State. We stress the importance of prenatal care as well. We don't disagree on that issue.

Senator WEICKER. I think this administration loves the publicity in these areas. When it comes to the bucks, and admittedly it costs money—it costs money—they are not willing to go ahead and put up the money to equate with their professed feelings on any subject.

When you and I went through our business on Baby Doe, one unfortunate baby, and I am glad the President gave all the attention to that baby, at the same time, we are cutting the budget for the retarded, those that are living. This is what I see here, all the business about abortions, Pro-Life, all the rest. When I begin to see something like that, I begin to truly wonder about the integrity of your intent. By that, I mean the administration, not you personally. Senator Proxmire?

Senator PROXMIRE. Senator Tom Harkin had to go to the Agriculture Committee where Secretary Block is appearing. I am going to make a statement and ask a question for him, and I will also ask a question for Senator Inouye.

Senator Harkin's question is this: As you know, the State of Iowa is predominantly rural in nature. The rural communities are being buffeted by the problems of the agricultural economy and high interest rates. The burden of the new Medicare prospective payment system has been especially heavy in light of these other factors. With 102 of Iowa's 129 community hospitals classified as rural under Medicare, this burden has been felt across our State.

One of the most serious problems with the Medicare prospective payment system is the measure being used to distinguish the DRG payment rates for urban and rural hospitals. That measure, the area wage index, was recognized as a problem by the 98th Congress.

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In the Deficit Reduction Act of 1984, we called on you and your Department to develop by August of 1984 an appropriate index for adjusting payment amounts to reflect area differences in average hospital wage levels, taking into account full and part-time workers.

REVISED URBAN-RURAL WAGE INDEX REPORT

We also required that appropriate payment adjustments be made based on this index. Finally, we required that your department study and develop proposed criteria by which an adjustment could be made in a hospital's wage index if the index did not accurately reflect the hospital wage levels in the labor market serving the hospital.

The question is this: When are we going to receive the report on revised urban and rural wage indices which was due last August? I understand in testimony before the House Appropriations Committee last Thursday you said the report was being prepared which would be used in the Medicare prospective payment program and would be transmitted to the Congress in 2 weeks. By my calculations, that would be Thursday, March 14. Will you still be meeting that deadline?

Secretary HECKLER. It should be ready for my signature by the end of this week, and it will then be sent to OMB. It will be ready from the point of view of HHS.

Senator PROXMIRE. So that you are saying the report will be before you this week?

Secretary HECKLER. Yes; and if I might just recite——

Senator PROXMIRE [interposing]. How long would you expect it would take OMB to receive the report?

Secretary HECKLER. I would hope they would expedite it, but it is a very complicated issue. First, I would very simply like the record to show that, as Department officials have said before, the designation of rural and urban areas was not HHS' proposal. This was a congressional mandate.

Second, there was no appropriate index which measured hospital wages. In the absence of any index that was absolutely accurate in terms of reflecting the conditions at hospitals, Bureau of Labor Statistics data was accepted. The Congress, and in particular, members from rural areas, then saw that this index was not appropriate, because it did not assess appropriately part-time workers. There was an understatement of costs at rural hospitals which have many part-time workers.

This necessitated the request in July for a new report. The Department established a working group on this subject—which included representatives of the hospitals from rural areas—to try to design an index that would be appropriate for them. We then went out and surveyed the third-party carriers for their information on wages in the various hospitals across the country. Their data was not sufficient, so we went directly to the hospitals. A third report was required after I received a draft report on the second survey which indicated that in the number of hospitals, there could be variations in cost and in reimbursement as high as 10 percent. That would be over $1 million for one particular hospital.

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I directed our inspector general to conduct a special audit of all hospitals with a differential of over 10 percent, simply because a change of that magnitude could be devastating to a hospital. That report differential has been prepared and is going to be coming to me this week.

The study, however, is of mixed value. While the wage index for certain areas will go down; for others it will go up. And it is not going to be, I think, the anticipated document making conclusive recommendations on changes in reimbursement.

Nonetheless, it will be available to OMB, and we will certainly prompt them to respond to it very, very quickly.

Senator PROXMIRE. Thank you. Senator Harkin had four other questions and I will ask you to respond to those, if you would, for the record.

Secretary HECKLER. I would be happy to.

APPOINTMENT OF SOCIAL SECURITY COMMISSIONER

Senator PROXMIRE. Senator Inouye is at a leadership meeting. He would like an explanation as to why HHS requested a rescission of the $2.5 million appropriated for the Pacific Basin Medical Officer Program.

On January 31, I pointed out on the Senate floor that Martha McSteen was eminently qualified to be Social Security Commissioner. She has had a long record of service in the Social Security Administration--20 years or so—and at every level she has been commended and congratulated. People have said she is an outstanding star, and in a well-run private business there would be no question of her not getting the job in view of the limited qualifications of her competitor for the job, Dorcas Hardy.

Had I known that Sandra Smoley, a Sacramento County supervisor, was in the running, I would have also questioned her suitability for the position.

Can you tell me when the Social Security vacancy will be filled and whether Mrs. McSteen is still a possible appointee?

Secretary HECKLER. I selected Ms. McSteen as the Acting Commissioner because of her record and her experience. I am very impressed with her, and I feel she has done an outstanding job. I would note, however, that the usual approach for any administration is to choose a political appointee for positions of this type. I would be very, very satisfied with Ms. McSteen, whom I supported earlier.

Senator PROXMIRE. I understand that, too. Ms. McSteen has been a faithful supporter of this administration. She hasn't been critical of the administration in any way. There have been no policy differences. She has a superb and extensive background. I believe we would have a far more efficient Federal Government if more people were appointed from within as a reward for the services they perform, especially when you get a real winner like Ms. McSteen.

Secretary HECKLER. She is outstanding, and I am very, very satisfied with her. The consideration of other candidates is an item I am discussing with the White House personnel office.

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Senator PROXMIRE. Can you tell me when a decision will be made on a new Social Security Administrator?

Secretary HECKLER. I cannot.

Senator PROXMIRE. How about the Assistant Secretary for Planning and Evaluation, has that position been filled and, if not, when will a nomination be submitted?

Secretary HECKLER. This, again, is on the agenda for discussion.

Senator PROXMIRE. When will an Assistant Secretary for Health be named?

Secretary HECKLER. I have made a proposal there, and I am awaiting their response.

HIRING AND ADVANCEMENT OF WOMEN AND MINORITIES

Senator PROXMIRE. Last year, you provided a table for the hearing record which indicated between 1981 and 1983, women in executive level jobs went from 12.7 percent to 14.6 percent. On the other hand, blacks in executive level jobs actually dropped from 7.7 percent to 7.5 percent between 1982 and 1983.

Can you give us the latest statistics and tell us what initiatives you are pursuing in that area?

Secretary HECKLER. We are still continuing our initiative on minority hiring and advancement of both minorities and women. I have a table which I can submit for you that does indicate growth.

[The information follows:]

Question. Will you provide for the record the percentage of blacks and women holding jobs at the GS-12 and above level at HHS for the last of the 2 years, and also provide data for each of those years showing what percentage of total HHS work force is made up of blacks? Can you do that?

Answer. Yes, sir.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

EMPLOYMENT OF WOMEN AND BLACKS WITH PERMANENT APPOINTMENTS 1983-84

Employee categories	December 31, 1983		December 31, 1984	
	Number of employees	Percent of total	Number of employees	Percent of total
Blacks:				
GS-12-15	3,406	12.1	2,523	13.5
SES/Exec	39	7.3	39	7.2
Total, all black employees	36,150	24.0	31,970	24.2
Women:				
GS-12-15	8,517	30.3	6,685	35.7
SES/Exec	76	14.3	81	15.2
Total, all women employees	95,354	63.2	84,527	64.1

NOTE.—Totals include Commissioned Corps and Wage Board employees, as well as employees in the GS, GM, SES, and Executive series.

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GROWTH RATE FOR WORKING WOMEN

Secretary HECKLER. In the last 3 years, there has been an average growth rate of about 13 percent in terms of the advancement of women——

Senator PROXMIRE [interposing]. The percentage of women in executive level jobs went from 12.7 to 14.6 percent between 1981 and 1983. What happened in 1984?

Secretary HECKLER. In 1984, from 14.6 percent to 15.1 percent.

Senator PROXMIRE. The percentage of blacks in executive level jobs actually dropped between 1982 and 1983. What happened in 1984?

Secretary HECKLER. The rate for blacks actually has dropped. It is 7.2 percent.

Senator PROXMIRE. The percentage dropped again?

Secretary HECKLER. Yes; from 7.5 to 7.2.

Senator PROXMIRE. That is a matter of concern, especially in a city which is 70 percent black. Why can't we make progress there?

Secretary HECKLER. Actually, the Department has faced certain changes in personnel. Once the election is over, there is a changing of the guard, and I would hope that with some of the posts being filled, this figure will improve.

Senator PROXMIRE. Will you provide for the record the percentage of blacks and women holding jobs at the GS–12 and above level at HHS for each of the last 2 years, and also provide data for each of those years showing what percentage of the total HHS work force is made up of blacks and women? Can you do that?

Secretary HECKLER. Yes, sir.

[The information follows:]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Employment of Women and Minorities
With Permanent Appointments
1980 - 1984

Employee Categories By Grade	December 31, 1980 Number of Employees	December 31, 1980 % of On-Board	December 31, 1982 Number of Employees	December 31, 1982 % On-Board	% Change FR. 1980	December 31, 1984 Number of Employees	December 31, 1984 % On-Board	% Change FR. 1980
1. Black								
GS 1-8	23,720	30.6%	23,478	32.7%	+ 2.1%	20,195	33.8%	+ 3.2%
GS 9-12	7,378	15.4	7,734	16.4	+ 1.0	7,911	17.1	+ 1.7
GS/GM 13-15	1,591	9.5	1,631	9.8	+ .3	1,545	9.7	+ .2
SES/Exec.	45	8.1	43	7.7	- .4	39	7.2	- .9
Total	32,734	22.9	32,886	24.1	+ 1.2	29,690	22.6	- .3
2. Hispanic								
GS 1-8	3,491	5.0	3,535	4.9	- .1	2,840	4.8	- .2
GS 9-12	1,876	4.0	2,059	4.4	+ .4	2,084	4.5	+ .5
GS/GM 13-15	405	2.4	434	2.6	+ .2	381	2.4	--
SES/Exec.	4	.8	3	.6	- .2	3	.6	- .2
Total	5,776	4.0	6,031	4.4	+ .4	5,308	4.0	--
3. Native American								
GS 1-8	4,505	5.8	4,176	5.8	--	3,826	6.5	+ .7
GS 9-12	1,025	2.2	1,109	2.4	+ .2	1,261	2.7	+ .5
GS/GM 13-15	174	1.1	185	1.1	--	206	1.3	+ .2
SES/Exec.	3	.6	1	.2	- .4	3	.6	--
Total	5,707	4.0	5,471	4.0	--	5,356	4.1	+ .1
4. Asian-American								
GS 1-8	859	1.1	832	1.2	+ .1	622	1.0	- .1
GS 9-12	730	1.6	731	1.6	--	741	1.6	--
GS/GM 13-15	370	2.2	386	2.3	+ .1	398	2.5	+ .3
SES/Exec.	6	1.1	8	1.4	+ .3	11	2.0	+ .9
Total	1,965	1.4	1,957	1.4	--	1,722	1.3	- .1
5. Women								
GS 1-8	65,646	84.5	61,380	85.4	+ .9	51,392	86.0	+ 1.5
GS 9-12	26,455	55.2	26,883	56.9	+ 1.7	27,054	58.5	+ 3.3
GS/GM 13-15	3,622	21.5	3,756	22.6	+ 1.1	3,793	23.8	+ 2.3
SES/Exec.	74	13.3	76	13.7	+ .4	82	15.2	+ 1.9
Total	95,797	66.9	92,095	67.5	+ .6	82,321	62.7	- 4.2

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CHILD CARE

Senator PROXMIRE. Madam Secretary, last month the department issued day-care guidelines to serve as model standards for States sharing $25 million in Federal day-care training funds that are targeted at the problem of child abuse. The standards have been criticized by several experts, some of whom have taken exception to the department's finding that it was infeasible to formulate standards that all States should follow.

Back in 1980, the Federal Government put together Federal interagency day care requirements—standards for federally supported day care centers—with the help of dozens of child-care specialists. Why weren't those standards incorporated into the guidelines you promulgated last month?

Secretary HECKLER. In 1980, the proposals and the standards were set by the Carter administration, and I think it is obvious that when President Reagan took office in 1981, the whole attitude toward the issue of day care changed.

The Department has had many discussions about child care, and many of the proposals that were acceptable——

Senator PROXMIRE [interposing]. Can I interrupt you? It is true that the 1980 standards were formulated in the previous administration, but these were put together by child-care specialists in a nonpartisan professional manner, were they not?

Secretary HECKLER. There was a totally different attitude, though, in the Department and in the society. For example, in 1980, the Government was still in a regulatory mode, whereas in this administration, we are trying to reduce regulations. There is much more flexibility.

This administration has supported day care, and certainly child care—in fact, we have through private sector initiatives really encouraged the development of more child care——

Senator PROXMIRE [interposing]. How can you get away without regulations when you are dealing with child abuse?

Secretary HECKLER. Yes; you need regulations, but I think the number of regulations which were envisioned in 1980 would be totally unacceptable in 1984, whether you are a Democrat or a Republican.

In 1985, the country's attitude has changed on child abuse. The most important problem that our guidelines address is the need to have a thorough search of the records of individuals who are seeking employment in day care centers. That can be done, and should be done, through implementing a change in State laws to require fingerprinting and reviews of criminal records. That, in itself, should be a major way to weed out the problems that have occurred since many of the people who have surfaced as abusers in child care centers have had previous experiences that should have been identified by the director of the center. We feel that is a critical change.

We are also encouraging parents to be very aggressive about visiting the child care centers, and we are also going to create a National Center for Excellence on Child Abuse. The Department has funded about

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100 million dollars' worth of research on child abuse. The recent tragedies focused attention on child abuse.

The time has come to implement that research, but in different States and in different ways from the earlier proposals, because the child care center itself has changed. There are small neighborhood child care arrangements with families in homes and in neighborhood centers. There are large centers; there are Head Start centers. There are a whole variety of centers and arrangements that were not envisioned in 1980. The biggest gain in new child care facilities has been made through corporate child care programs. That is something we strongly stressed in the private sector initiative. The increase in child care facilities has been over 300 percent.

MATERNAL AND CHILD HEALTH

Senator PROXMIRE. Let me ask one more question. My time has run out. A recent study by the Institute of Medicine proposed a more aggressive preventive approach to the reduction of low birth weight babies. The Institute's study states that this tactic "may well prove to be considerably less costly, both socially and economically, than additional investments in the salvage efforts of neonatal intensive care."

In 1981, about 250,000 newborns, 6.8 percent of the total, weighed 5.5 pounds or less. These children are almost 40 times more likely to die during their first month and have twice the risk of normal babies in developing cerebral palsey or being mentally retarded.

Is the department considering any program enhancements that would target prenatal care to those who are at greatest risk of having low birth weight babies—women between the ages of 15 and 39 who receive welfare and have less than 12 years of education? This might be a very cost effective way to go.

Secretary HECKLER. I agree. We are trying to target our resources in this area. We are implementing the law which requires that Medicaid fund prenatal care for pregnant women. In addition to that, we are in the process of creating teams of experts from the Department who will work with the maternal and child health grant directors in the specific areas in which the problem surfaces most dramatically. In certain cities, it can surface on an unpredictable basis, as Boston indicated last year.

What we are trying to do is create teams of specialists—the best resources—who will work with maternal child health directors in the local areas.

We are also working with States and urging them to target resources to the areas in which the problem exists. I could inundate this committee with work the Department has done on the subject. It is a matter of grave concern.

At the same time, we do believe that our 1990 goal on infant mortality is going to be achieved. Overall, infant mortality is decreasing, among both black and white babies. While the rate of decrease has slowed, the direction remains the same. We, in fact, feel that our goal for 1990, which is to have no more than 9 deaths per 1,000 live births, will not only be achieved, but exceeded.

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Senator PROXMIRE. Thank you. Thank you, Mr. Chairman. And thank you, Madam Secretary. Madam Secretary, I am going to submit questions for the record.

Secretary HECKLER. We will be happy to answer them.

MINORITY HEALTH EDUCATION

Senator WEICKER. I have questions from Senators Specter and Andrews, which will be submitted, Madam Secretary, for your response to the record.

Last year, you requested an additional $6 million, above the $18 million we provided in fiscal year 1984, for the Disadvantaged Assistance Program. You emphasized in your statement that these additional funds were needed in order "to maximize the opportunities for minorities and the economically disadvantaged to enter health professions careers." Congress provided the additional funds you requested, and the appropriation now stands at $24 million.

Why then this year you request not one nickel for the program?

Secretary HECKLER. Mr. Chairman, the needy students will have access to student aid. There is $67 million available, in the health professions and the nursing student loan revolving funds, and $100 million in new loan guarantees under the Health Education Assistance Loan Program, [HEAL]. That source of funding will be available.

The minority medical schools are very much on the way to improving their own financial situation—their debts are reduced, tuition increased, and private funding for them is up. We have provided 4 years of advanced financial distress assistance to minority medical schools, $5.5 million in 1985.

This year, we have begun a new initiative, the NIH's research centers at minority institutions awards and academic research enhancement awards will be coming on line in 1985 and continued in 1986. For the first time, this will allow minority medical schools to participate in our national research environment.

Again, overall reductions were made in view of the fact that there were revolving loan funds available. It was decided that they would be the primary source of funding for minority students.

Senator WEICKER. Those same funds were available last year.

Secretary HECKLER. They were.

Senator WEICKER. Why the urgency last year?

Secretary HECKLER. The financial situation of the medical schools has improved considerably. We have been part of this improvement as has the Congress.

We did create a special fund for minority medical schools in financial distress.

Senator WEICKER. I understand that. Last year, it was one of the few times the administration asked for additional funds, $6 million to maximize the opportunities for minorities and the economically disadvantaged to enter health professions careers.

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The programs you refer to were in place then. Obviously, you thought that was especially important. Was this a 1-year deal, one-shot deal? I don't understand.

Secretary HECKLER. The priorities of the current situation require decisions to not fund many of the programs that we supported——

Senator WEICKER [interposing]. In other words, the answer is, in this case, we are talking minority and economically disadvantaged, this is now sacrificed to balance the budget.

Secretary HECKLER. As well as all the other grants for medical and nursing students. The minority programs will have the same experience as the others.

COMMUNITY SUPPORT PROGRAM

Senator WEICKER. Once again, you propose to eliminate funding for the Community Support Program, the only Federal program targeted toward developing and improving community support services for the chronically mentally ill, and Congress has never gone along with the proposal in any of the 5 years this administration has tried to terminate it and, in fact, approved a 50-percent increase to $10.5 million last year for the Community Support Program.

As you know, one of the target populations of this program is the homeless mentally ill, who may number as many as 1 million persons.

At a time when concern over the plight of the homeless has become front-page news, how do you justify eliminating the one Federal program which has attempted to address the unsolved problems related to deinstitutionalization?

Secretary HECKLER. That is a very small program which does deal with the problems of the mentally ill. As we look at the total budget, again, the alcohol, drug abuse, and mental health services block grant was preserved intact and frozen. Frankly, that is a much larger source of funds for the needs of the whole constituency. As we looked at the budget, this was simply not a high priority program compared to others. In fact, the mental health block grant should provide funding for the needs of those who are mentally ill among the homeless.

That segment of the homeless is on the streets because of their mental health problem and because they were deinstitutionalized without alternate shelters.

STATE SURVEY AND CERTIFICATION

Senator WEICKER. The Department of Health and Human Services has the authority to monitor psychiatric hospitals participating in the Medicare and Medicaid Program to make sure that health and safety standards are met, and that active treatment is provided to residents of those facilities, as required by law.

However, in the course of my staff's recent investigation of conditions in State psychiatric hospitals around the country, it became clear, as we found last year in the ICF's/MR, that HHS is not aggressively monitoring these facilities.

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What do you believe is the appropriate HHS role in assuring that high quality care is provided in these institutions and what steps do you believe the Federal Government should take to rectify the deplorable conditions that are still all too common in these facilities?

Secretary HECKLER. We are very concerned. As you know, and as I believe your staff knows, we are aggressively pursuing the improvements in the ICF's/MR. In terms of the psychiatric hospital surveys, currently facilities that have the Joint Commission on Accreditation of Hospitals [JCAH] accreditation need to be surveyed for two additional conditions to meet the qualifications for participation in the Medicare and Medicaid Programs.

First, there are expanded staffing requirements. They ensure that a higher quality of care is provided to patients, since there would be not only a better ratio of classifications, but a multidisciplinary team to provide treatment.

Second, there are enhanced medical records requirements. This enhances the documentation of treatment standards and provides both long and short-term treatment planning. The review of whether facilities meet these conditions may be done by Federal psychiatric clinical consultants or by State survey certification specialists.

Psychiatric hospitals not accredited by JCAH must meet not only the two special conditions for psychiatric hospitals, but also the basic conditions for participation for general hospitals—that is, medical staff, dietary, et cetera.

The State survey agency conducts the onsite survey; the State agency surveyors are health professionals trained to evaluate facility compliance with Federal health and safety requirements.

Hospital surveys are generally announced at least 2 to 3 working days before they commence. It is important for key staff to be available for interviews. As a result of complaint or allegations regarding the failure of Medicare and Medicaid hospitals to comply with the conditions of participation, unannounced visits also have been made by HCFA regional staff with assistance from State agency surveyors.

HCFA supports State survey and investigates the standards—whether or not the psychiatric hospitals are meeting our standards for participation.

Senator WEICKER. Out of 440 facilities, 2 were surveyed by HHS to see if the JCAH standards were met. That is 5 percent. Do you think that is adequate?

Secretary HECKLER. When a deficiency is found in these facilities, the facility must submit a plan of correction which addresses the deficiency. In the case of a life-threatening deficiency——

Senator WEICKER [interposing]. My question related to, in other words, only 2 out of 440 surveyed by HHS; I asked if you consider that an adequate figure?

Secretary HECKLER. The information I have here is that, in the most recent surveys of 411 providers, approximately 7 percent were out of compliance on the medical records requirement and 7 percent were out of compliance on the medical staffing requirement.

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My information indicates the survey was on 411 providers. I would have to ask for an update on this.

Senator WEICKER. Would counsel like to comment on that? Is that correct? Jane West is staff director of our Handicapped Subcommittee.

Ms. West. HHS has for psychiatric——

Secretary HECKLER [interposing]. Senator, I have Jim Scott with me today who is the Acting Deputy Administrator of HCFA. Perhaps he can respond more precisely to this.

Senator WEICKER. What is the correct figure? How many are we serving?

Mr. SCOTT. Sir, I don't know the exact numbers. I would like to respond to the process of the validation survey. These facilities have been surveyed and accredited by the Joint Commission on Accreditation of Hospitals. They have a standard set of rules and a standard survey protocal. The Commission is a well-established organization, with an excellent track record for these kinds of accreditation.

In the validation process, we test on a sample basis—it is a 5-percent sample in this case—to make sure the processes they use have yielded the kind of results that we want. We want to make sure that their requirements are addressing the issues we feel are important.

Senator WEICKER. What you are saying, you are not disagreeing with the 5-percent figure.

Mr. SCOTT. I am not disagreeing.

Senator WEICKER. You are saying the initial accreditation——

Mr. SCOTT [interposing]. Correct.

Senator WEICKER. Which I don't dispute.

Mr. SCOTT. We are just doing a validation that the status——

Senator WEICKER [interposing]. Do you think things can go downhill? I don't assume anything. You do 5 percent of these a year; is that right?

Mr. SCOTT. Again, Senator, what we are looking for is a process whereby we may test the adequacy of the joint commission process, its procedures, and its standards. These facilities have a deemed status and we think this is an adequate sample.

If we found consistent difficulties, we would look to see if there had been a deterioration of the joint commission survey process. If there were individual kinds of difficulties; we would work closely with the joint commission to see why the facilities had a problem.

Senator WEICKER. What is it, the first, second, third of April?

Ms. WEST. Yes.

Senator WEICKER. On the 1st, 2d, and 3rd of April, I am going to let the country get first hand from the people in these institutions what it is that is going on and, believe me, you better be prepared for a tornado at your door. We are going to start making come real all these acronyms, all these budget figures, and the effect they are having—who is doing what, who is not doing the duty assigned to them.

I can assure you by the time those hearings are over, the figure will not stand up to any kind of bureaucratic explanation.

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What is your procedure for referring cases of abuse and neglect in the psychiatric hospitals to the Department of Justice and how often has this been done?

Secretary HECKLER. Would you please respond?

Mr. SCOTT. Senator, I am not familiar with the exact details of how that process works. We do work with the Department of Justice when the complaints come in, both in psychiatric hospitals and the ICF/MR facilities. We will supply for the record the exact numbers of cases that have arisen.

RESIDENT TRAINING IN ICF/MR

Senator WEICKER. My last question and then I will let Senator Specter ask his questions.

Your inspector general recently recommended withholding $34 million in Federal Medicaid funds spent on training of residents in ICF/MR. The inspector general estimates that Federal Medicaid savings would total $585 million over the next 5 years if these funds are withheld.

What is the rationale of withholding these funds, which I understand are used to pay for such rehabilitation activities as toilet training and self-feeding skills?

Secretary HECKLER. I would like Jim Scott to respond to that. I haven't been informed of that.

Mr. SCOTT. There was an inspector general survey, as you indicated, Senator, in which they looked at some of these issues. It comes down to questions such as what activities are medical in nature, and what activities are educational in nature.

We are in the process of taking a look at that and discussing the issues with them. I think it is safe to say that there are two viewpoints on this. As we look at his findings, and in our own analysis, we want to make sure we are not overly hasty and come down on one side or the other prematurely.

Senator WEICKER. Well, I would hope so. I don't think matters such as I have indicated are going to balance the budget. Senator Specter?

Senator SPECTER. Thank you very much, Mr. Chairman. At the outset, Senator Weicker, I certainly commend you for your diligence in chairing this very important subcommittee. I came here earlier and wanted to come back to give you some support and some company on the subcommittee.

Secretary Heckler, I know that your job is a very difficult one. You have been here for more than 2 hours so far. Some of the cross-examination that I have been present for has been directed and pointed, and I commend you on the job you are doing.

I know it is a very difficult job with an enormous Department, and one of the concerns that I have as to whether we might be able to give you help sometimes on responding to some of the inquiries which we make because they are not as prompt as I know you would like to make them back, and they are not as prompt as those of us in the Senate would like to see some of the answers.

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Perhaps there is some way we could give you some help in your own budgeting to give you the kind of staffing you need. There is only so much you can do or any one person can do. Let me take up a couple of specifics with you.

ADJUSTMENT OF PPS RATES

I wrote to you back on January 24 on an issue where the Department had not provided for adjustments and exceptions to the prospective payment rates for hospitals serving a significantly disproportionate number of low-income Medicare patients as authorized by the 1983 amendments. And this, of course, is a national problem. It is especially acute in Pennsylvania where we have many hospitals eligible for adjustments or exceptions. The date set for establishing these guidelines was to be December 31, 1984, as a deadline.

As I understand it, that was not done, and some 6 weeks have elapsed since I wrote to you on January 24 and I really have two concerns, Secretary Heckler.

First, the substance as to what will be done on this matter and, second, how you organize your office and the responses to try to deal with it in a timely way.

Secretary HECKLER. Answers to some of the questions that were asked require both field investigations and study teams. To draft policy responses in the prospective payment area, for example, as we plow new ground, the fast, efficient answer is not always the thoughtful and accurate one. Responding to questions about hospitals, my greatest concern is to provide as accurate a response as possible to the questions that are raised.

In this particular case, you refer to a requirement in the Social Security Amendments of 1983 which made an exception or adjustment to the prospective payment rates as deemed appropriate for hospitals serving a significantly disproportionate number of low-income or Medicare patients.

HCFA conducted a number of studies to determine if these hospitals do, in fact, incur higher operating costs as a result of the types of patients served by the facilities. The studies have found the costs are not higher in hospitals serving that particular constituency. Therefore, we determined there is no justification for providing an exception or an adjustment to the PPS rates.

I will say that the American Hospital Association has conducted a similar study and has found the costs are higher in these hospitals. HCFA will be reviewing the AHA study to assess its validity and to determine whether or not any change in policy is warranted on our part. We will be responding on this issue.

The Deficit Reduction Act of 1984 requires that a definition be developed of a hospital serving disproportionate numbers of low-income or Medicare patients and that a list of hospitals meeting that definition be developed and provided to Congress. HCFA is currently working on the definition, and it is also reviewing its own study in the light of the AHA finding.

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Senator SPECTER. Secretary Heckler, the information I have is that there is a very significant difference in the costs serving those low-income and Medicare patients. Unfortunately, you can find a survey which will prove just about anything.

Secretary HECKLER. That really was not the attempt. I have to say on behalf of the HCFA staff, I don't believe they prejudge the results of any survey they have conducted. At least, that has been my experience. I don't believe there was any attempt to study a problem and reach a preconceived conclusion. In this case, we will do a study and reconsider our position.

HEART TRANSPLANTATION

Senator SPECTER. I appreciate your doing that as soon as you can because the information I have gotten is very solid. There are very substantial differences in costs.

Secretary Heckler, I wrote to you back on December 28 concerning the issue of heart transplants to try to take it out of the experimental category so that those procedures would qualify for Medicare and other third-party payments.

We have some very outstanding institutions in Pennsylvania—Presbyterian Hospital in Pittsburgh and Hershey Medical Center, which I have seen. There are major concerns now the process is very far along—liver transplants, heart transplants—to have an evaluation by your Department which would take them out of the experimental category so they can qualify for Medicare payments and the insurance companies follow along, and as long as your Department says it is experimental, the third-party payments won't respond either. I would be interested in your thinking on that subject.

Secretary HECKLER. In Massachusetts, the third-party payers have instituted a special coverage for transplants. The Department has awarded a contract to the Batelle Institute to review the efficacy and cost and quality of life implications associated with heart transplant surgery. Both HCFA and PHS have reviewed a draft report on the study and have provided comments to Batelle. We have not received a final report from Batelle and that will be important in terms of our own consideration.

Transplantation expertise is advancing in every field. We are reviewing potential eligibility under Medicare for heart transplants and for a number of other transplants. There are many unresolved problems that have not yet been answered. It seems that our technology and our surgical expertise is developing, but there is a need to review all of the unresolved questions on quality of life, the cost implications, and the survival rate.

We have to handle these issues very, very carefully. They pose very difficult questions as we also face the financial limitations of the Medicare Program, its inevitable bankruptcy. The postponement of the insolvency of Medicare has been postponed by some estimates until 1993. In our society, numbers of those reaching the over 65 category are

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increasing at a very, very fast pace, and we must recognize the burdens on a system which will be strained. To deal with the many issues, it will have to be addressed by the Congress ultimately.

In the interim, we are assessing new transplantation approaches and surgery, the new technology. They are equitable questions raised about what we fund. Do we spend more money on primary care? Do we spend more money on sophisticated complex surgery on a few? To make those decisions that judgment poses a serious and weighty ethical problem. There are ethical questions here, and there are policy questions for Medicare, and we have not yet reached the point of making any decisions.

Senator SPECTER. Secretary Heckler, when you talk about the burden on Medicare, I think you really come to the point of it. When we consider whether heart transplants or liver transplants or kidney transplants in the experimental category ought to be taken out, I think it is a different issue. There were approximately 300 heart transplants performed worldwide in 1984.

It seems to me that category of medical procedure is out of the experimental stage. The concern that I have is that so many judgments are being made, it seems to me, on the basis of what Medicare can afford. I would come back to the question that I asked about the adjustments or exceptions for prospective payments for hospital patients, low-income or Medicaid patients for heart transplants. I believe it is really objectively not appropriate to consider the burden on the Medicare system—this is something this subcommittee and Congress has to do—and it is a different question and too often, I am concerned that your Department is concerned about the burden to the system, and that really is our question.

We have defined, we have tried to define the objective standards for when your Department pays money for certain things, and the studies go on very, very long. I know they are important, but it seems to me that you have got to really separate what you can afford to pay for or do, the administrative function of measuring up the definitions for what Congress has said.

Secretary HECKLER. I think the prospective payment issue is one that clearly has to be addressed immediately, since there is this contradiction between the two studies. This will have to be reviewed. We definitely will respond to your interest on that subject, and we will respond this year on prospective payment changes if the study warrants it.

We will be rewriting the prospective payment regulations, as you know. Although we do have a budgetary freeze, the budget will be a factor in our judgments. But, the needs of the people have to be our primary concern, and they are.

The transplantation issue is one that is not as clear cut. There have been great new breakthroughs, there are still questions about what the quality of life is, what the survival rate is—there are many factors this Batelle study will look into.

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It is our goal to meet peoples' needs as fairly as we can, and I have to say that goal is really superior to the goal of facing the budget.

HOME SHELTERS

Senator SPECTER. I have a number of questions which I will submit for the record. I know time is short here. I would just ask one final question, and that relates to the homeless shelter here in the District of Columbia. That is an enormous problem around the country, the problems of the homeless all around this country; that is an enormous concern.

I have had some special activity on the District of Columbia issue.

Secretary HECKLER. You have.

Senator SPECTER. Because I chair the Subcommittee on the District of Columbia and worked with you when you had an emergency.

Secretary HECKLER. You did.

Senator SPECTER. About 1½ years ago.

Secretary HECKLER. Thank you for that.

Senator SPECTER. One of our hearings disclosed some real questions about the shelter, so I decided—I cut the hearing short, stopped listening and started walking and went over to the shelter, and it was just awful. It was just an absolute cry. They serve 800 people over there, and they don't have any toilets. The toilet room is a flooded area. They have kitchens which if you ate on the floor, it would be the same as eating from the counters or the tables, and it was just really the most disgraceful situation there.

I wrote to you back on January 28 about the visit which I made a few days earlier. I won't ask any questions about it unless you want to respond, but I would urge you—I will cut my questioning short now and give you time to go over and take a look at it, but I think if you did see it, we just have to do something in a joint way about that shelter.

Secretary HECKLER. Senator, we have already invested $85,000 in renovations. Ultimately, the Federal Government will fund renovations of about $5 million. We feel there should be a sharing of other departments in this venture, in this whole shelter funding: it will not be our Department exclusively.

I personally opposed that particular shelter and tried to work with the Mayor to find another. We suggested to him 17 other sites for shelters. The Federal City College Building is very large. As you know, it is composed of classrooms and it really was not conducive to use by homeless. I felt smaller shelters were more desirable. This, also, was not by any means an ideal location.

We reached no agreement, although I did have staff working with the Mayor's office for literally 6 months. I had a personal meeting with him. As the winter approached, there was no agreement on another location and then this shelter became the only option.

We agreed to renovate it. Now we are in the process of getting the architect's drawings to explore how the building can be brought to a decent living standard for those who are there.

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Hopefully, some of the conditions you saw have improved. The $85,000 did fund some basic renovations. We also expect that there will be very extensive renovations there in the very near future. I am very concerned about it, as you are.

Senator SPECTER. I will take another look and let you know.

Secretary HECKLER. All right.

Senator SPECTER. Thank you very much, Mr. Chairman.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much, Senator Specter. There are further questions which I am going to submit for response to the record. And I might add, not questions of mine, but just questions of other Senators on the panel. Thank you very much, Madam Secretary, for your testimony.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

SERVICE DELIVERY TO THE PUBLIC

Question: In view of the Administration's stand against cutting Social Security benefits, how can you be sure that services to the elderly will not be impaired by such a massive cutback in personnel?

Answer: The 17,000 reduction in full-time equivalents is based upon the successful implementation of the Systems Modernization Plan (SMP) as well as upon various improvements in Agency productivity. The SMP will eliminate some labor-intensive manual processes and will make information more readily available to our public contact personnel, resulting in shorter interviews and fewer recontacts.

The effect of the SMP improvements will be shorter waiting times, improved personalized service and fewer errors in processing claims. We are implementing the improvements in a deliberate manner to ensure that the systems work properly and deliver the anticipated savings with no deterioration in service quality, product accuracy or timeliness. The increased availability of information to our public contact personnel should, in fact, improve the quality of work products to such a degree that we will be able to eliminate many manual reviews, thus decreasing the time it takes to process actions.

Question: Do you have any studies to demonstrate that such cuts will not result in longer waiting lines, terse treatment of elderly persons seeking assistance and greater errors in processing claims which could result in more people being denied benefits to which they are actually entitled?

Answer: SSA continually studies proposed work processing changes to identify impacts on the delivery of service. This study process begins with the initial proposal for a change and continues even after implementation. One such change we are studying is the Modernized Claim System. As the project develops we are continually updating our impact estimates and refining the system requirements to ensure that the quality of service will not suffer. We will conduct pilot studies of the new system in two field offices initially, expanding the pilot study to 18 additional field offices once we are satisfied with the initial results. We are studying all aspects of the system for impacts on workflows, staffing mixes, processing times, product accuracy, and employee reaction, as well as the quality of public service. If there is any impediment in phasing in new modernized equipment, there will not be a phasing out of personnel. The equipment must be in place and the system working before the personnel are phased out.

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Question. The President's budget states that in 1986 private voluntary resettlement organizations would be used to provide for the basic needs for refugees for the first 90 days after their arrival in the United States.

Is it intended that refugees would cease to be eligible, during these 90 days, for refugee cash assistance (RCA) or AFDC?

Answer. Yes. We consider it important that a refugee not receive duplicative assistance from both a sponsoring resettlement agency and a public welfare agency. Such simultaneous receipt of assistance would be unnecessarily costly and would not reduce refugee dependency.

Question. What would be the effect on refugees if some of these organizations failed adequately to discharge their responsibilities toward them?

Answer. The resettlement agencies would be carrying out these responsibilities under agreements with the Department of State. They would receive Federal funds for this purpose, and in turn, would be responsible and accountable for providing the assistance required by the agreement. Under such an agreement, a resettlement agency would, in effect, be taking on the responsibility of providing a safety net for a refugee for a period of 90 days. We believe that an agency which the Department of State determined to be qualified and which entered into such an agreement would undertake to conscientiously fulfill this responsibility.

Question. The FY 1985 Continuing Resolution specified that for FY 1985 refugee assistance was to be at the lower of two rates:

- The current rate (i.e., $541.9 million for FY 1984);
- The amount authorized by the refugee extension bill as it had passed the House (i.e., the same or higher than the current rate in all categories except targeted assistance, which was $27.5 million lower).

In the face of this language, how did you determine that the amount appropriated for refugee assistance for FY 1985 was only $444.4 million?

Answer. The FY 1985 refugee assistance budget under the Continuing Resolution (CR) is the same amount as in FY 1984 for all categories, except targeted assistance, which is limited by the authorization in the refugee extension bill, and cash and medical assistance, and related administration (CMA). The latter category is lower in FY 1985 than in FY 1984, primarily because of a smaller 3-year eligible population in FY 1985. The average monthly 3-year eligible population during FY 1984 was approximately 230,000; in FY 1985, the monthly 3-year eligible population is only about 195,000. As a result, CMA needs in FY 1985 are estimated to be $70.0 million less than in FY 1984. As the Senator has stated, under the provisions of the FY 1985 CR, targeted assistance is limited to the amount authorized by the refugee extension bill as it had passed the House (i.e., $50.0 million, or $27.5 million lower than the FY 1984 amount for targeted assistance). The total of the decrease for CMA ($70.0 million) and targeted assistance ($27.5 million) accounts for the FY 1985 budget under the CR ($444.4 million) being $97.5 million under the FY 1984 budget (of $541.9 million).

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Training in the Prevention of Child Abuse

Question. The Fiscal 1985 appropriation earmarked $25 million under the Social Services Block Grant for training programs to combat child abuse in day care centers and other facilities for children. Do you feel that this money is being effectively used by the States?

Answer. The issue of child abuse and neglect is of considerable importance in the States at this time. I am confident that the one-time funds the States have received under the Social Services Block Grant will be used fully to initiate or expand training programs for the prevention of child abuse and neglect.

Question. Why don't you favor extending the authorization and appropriation of $25 million for child abuse prevention training in Fiscal 1986?

Answer. The appropriation of an additional $25 million for FY 1985 under the Social Services Block Grant was enacted as a one-year only financial incentive. Congress provided the funds to encourage States to enact requirements for background, employment history, and criminal record checks of persons hired to care for children, and to fund training of persons who are employed to care for children in the prevention of child abuse. States which do not enact statutory requirements for background checks will lose half of their share of the special incentive funds in FY 1986 or FY 1987.

We believe one year of special financial incentives to be adequate to encourage States to enact background check requirements and to begin regular training of child care employees in the prevention of child abuse. Fiscal year 1986 and subsequent year funds will continue to be available to States for training under the Social Services Block Grant and grants to States for the prevention and treatment of child abuse and neglect. Furthermore, in future years, once current child care employees have been trained, the training of new staff will require substantially fewer resources; additional funds will not be necessary to maintain training programs.

Question. What is the status of the Model Child Care Standards legislation called for by an amendment to the Fiscal 1985 Continuing Resolution?

Answer. The "Model Child Care Standards Act - Guidance to Prevent Child Abuse in Day Care Facilities" was completed in January 1985 and has been transmitted to each State.

Question: The Attorney General's Task Force on Family Violence recommended that "the Federal government should provide financial incentives and encouragement to the States to train criminal justice personnel, to conduct a family violence prevention and awareness campaign, and to maintain temporary resident facilities for victims of family violence." In view of this Administration report, why didn't you request funding to implement the recently enacted family violence prevention and services act?

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Answer: In September 1983, the Attorney General created a citizens task force to provide recommendations for action on the problems of family violence. The task force's final report recommended many actions at all levels of government, including Federal financial incentives for training, public awareness campaigns and temporary shelters for victims. However, this report has not been endorsed as Administration policy regarding the Federal role in addressing family violence.

The Administration's FY 1986 Budget does not request funds authorized in the Family Violence Prevention and Services Act because, in addition to budget constraints, we believe creation of an additional narrowly defined categorical program would be duplicative of existing Federal activities and inconsistent with Administration objectives to allow States and local communities maximum flexibility in addressing local problems. The most effective responses to the problems of family violence are those developed by local communities.

The Federal government already provides support to assist local governments in combatting family violence. In the Department of Health and Human Services alone, there are many programs which address different aspects of family violence. For example, the Social Services Block Grant provides funds to States which may be used for a wide range of social services, including those that may address family violence. The Child Abuse and Neglect Prevention and Treatment program assists States, local and voluntary organizations to prevent and treat child abuse and neglect. The Department also administers health block grants which can fund services to prevent and treat family violence. In addition, the Department funds a number of research projects related to family violence.

FACILITIES ENGINEERING

Question. Madam Secretary, Last year we recognized the lack of a Department request to support the activities of the regional office of facilities engineering and construction (ROFEC). We provided $6.2 million and 127 positions for this activity. For fiscal year 1986, you are requesting only $3.5 million and 69 positions. In addition, you are proposing to move all ROFEC personnel from San Francisco to Dallas, creating a situation where Hawaii would have to deal with Dallas, another time zone away. Is there some logic behind all of this which may not be readily apparent to some of us?

Response. The staffing number of 69 positions resulted from a detailed study of the Regional Operation for Facilities Engineering and Construction (ROFEC) operations conducted by the Department in early 1984 in conjunction with the Office of the Secretary streamlining effort. The study concluded that ten regional locations and 127 positions could not be justified because of declining workload, and recommended that 69 positions be allocated to service the workload in consolidated locations.

Dallas, Texas was selected as one of the three consolidated locations for its central location relative to the majority of its work for the Indian Health Service in the Southwestern part of the United States.

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The ROFEC work requirements in Hawaii have been minimal with no projected direct federal construction and very little federally assisted construction activity. However, you can be assured that Dallas will continue to provide the same level of service to projects in Hawaii as we originally provided by the San Francisco office.

MEDICAID HARDSHIP FUND

Question. The budget proposal for Medicaid estimates savings of approximately $1 billion in FY 1986, and total savings of up to $16.6 billion over 5 years, if your "cap" proposal is enacted. This cap would, in effect, turn the Medicaid program into a quasi-block grant, with States receiving the same proportion of the FY 1986 total of $22.2 billion as they did of the FY 1984 total. Also proposed is a "hardship fund" of $300 million to be available only in FY 1986 for States that experience extraordinary costs above their limit. How did you arrive at this $300 million figure for the hardship fund? Was this decision based on a realistic assessment of States' needs, or is this another example of OMB's handiwork?

Answer. We assumed that the "cap" proposal would give all States the incentive to adopt cost containment measures and improve program efficiency through a variety of mechanisms. It was recognized, however, that some States would have excessive cost increases in 1986 due to circumstances beyond their control (i.e., caseload increases, expanded eligibility, regional changes in economic circumstances), and the hardship fund was established to help those States. In developing the 1986 budget, it was determined that $300 million was an appropriate figure to cover "excessive" cost increases above and beyond the level at which States could be expected to achieve savings through implementation of cost control and efficiency measures.

HARDSHIP FUND CRITERIA

Question. What criteria will States be required to meet in order to tap this fund?

Answer. Although the exact mechanism for allocating these funds has not yet been determined, the criteria will target those States that experience extraordinary costs above their Federal limit despite sincere efforts to control costs within the constraints of their existing program. The following general criteria are being considered for the hardship pool:

- A State's spending for 1986 must exceed a certain threshold percentage above its cap.
- A State must give evidence of having taken aggressive action to contain costs in recent years.

DISTRIBUTION OF MEDICAID FUNDS

Question. Won't some States be unfairly penalized because all future Federal payments would be linked to payments made in FY 1984--the year that many States instituted significant program cutbacks.

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Answer. The proposed cap would distribute funds in 1986 on the basis of each State's relative share of payments received in FY 1984. We chose 1984 as the base year because it is the most recent year for which actual expenditure data is available. We realize that after 1986, there may be a need to reapportion funds based on changing State circumstances, and we will be examining criteria which might be used in making reapportionments.

MENTAL HEALTH CLINICAL TRAINING

Question. The budget for the Alcohol, Drug Abuse and Mental Health Administration once again proposes elimination of funding for clinical training of mental health professionals, despite Congress' disapproval of this request last year when we provided $22 million for this purpose. What information do you have to indicate that shortages in specialty areas targeted by Congress as deserving of special attention, such as child mental health care, no longer exist? When may we expect to receive the NIMH response, which was due with the submission of the budget, to GAO's report entitled "Effectiveness of Mental Health Clinical Training Programs Cannot Be Evaluated"?

Response. While there may well be shortages in a number of mental health speciality areas, we believe that long-term Federal support has developed a national training capacity to the point that these shortages can be addressed without continuing Federal subsidies. The NIMH response on the GAO report is contained in the "Report on Clinical Training Allocation Policies" submitted to the Committee on February 25, 1985.

MEDICAID STATE FLEXIBILITY

Question. The President's budget announced that the Administration proposes substantial new program reforms to increase significantly the States' ability to control Medicaid costs. These reforms are claimed to include "increased flexibility to target services and offer alternatives to more costly services." Could you explain in greater detail what, specifically, is intended?

Answer. The details of these flexibility proposals are still being worked out. We are looking comprehensively at many components of the Medicaid program, including those pertaining to eligibility, services and coverage, reimbursement, cost sharing, and administration. These proposals are intended to increase State flexibility in managing their Medicaid programs, reduce burdensome administrative requirements, and allow broader latitude in defining eligibility and the scope of services provided. We expect to have concrete proposals within the next month.

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STATUS OF HOSPITAL INSURANCE TRUST FUND

Question. The 1984 Trustees Report, submitted to Congress last spring, indicated that the Hospital Insurance Trust Fund would be exhausted in 1991. Has this projection been updated?

Answer. The projection on the status of the trust fund has not been updated yet. The Department is in the process of updating its projections and current information will be contained in the 1985 Trustees Report which will be available this spring.

Question. What is the current status of the fund?

Answer. As you have indicated, the 1984 Trustees Report projected that the trust fund would be exhausted in 1991 based on the alternative II-A and B assumptions. The proposals included in the FY 1986 budget will, of course, have an impact on when the trust fund will be exhausted. More current information will be available as part of the 1985 Trustees Report which will be submitted to Congress this spring.

Developmental Disabilities Study

Question. The recently reauthorized Developmental Disabilities Act requires you to prepare and submit a report to Congress by April 19, 1985, recommending ways to improve services for residents of ICFs/MR, including movement into more appropriate community settings. How are you involving the Office of Special Education, the Administration on Developmental Disabilities, and the National Council on the Handicapped, in the development of this report, as required by law?

Answer. The report is in draft and is undergoing an internal review which includes review by the Administration on Developmental Disabilities. When the departmental review is complete, the report will be shared with the Department of Education and the National Council on the Handicapped.

Question. Will this report by completed on time?

Answer. The Department is making every effort to ensure this report illustrates national, State, and local efforts to promote the independence and integration into the community of developmentally disabled people. The Department is proceeding with the concern and care such a major assignment deserves.

The report will be completed for external review by April 19. Since the legislation requires the report be commented on by several agencies, it is possible additional time will be necessary to complete this process.

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NEW ICF/MR SURVEYOR AND DEVELOPMENTAL DISABILITY SPECIALIST POSITIONS

Question. Whose decision was it to recruit for only 45 new staff instead of 57, as Congress intended? Was OMB involved in that process?

Answer. This decision was made independently by the Health Care Financing Administration. It was considered the most expeditious way to obtain qualified surveyors for this function. The Department is committed to maintaining a staff of 57 for ICFs/MR "look-behind" surveys as intended by Congress and plans to hire qualified surveyors and developmental disability specialists as needed to meet this objective.

NEW ICF/MR SURVEYOR AND DEVELOPMENTAL DISABILITY SPECIALIST POSITIONS

Question. Since we provided you with sufficient funds for 57 new positions and you are only recruiting outside for 45 of those, what do you plan to do with the funds that will not now be needed?

Answer. The $1.9 million earmarked for ICFs/MR "look-behind" survey positions will be spent as intended. The funding provided for this purpose has been incorporated into the total amount of budget authority available to the Health Care Financing Administration (HCFA) in FY 1985. Of the proposed FTE ceiling of 3980, 57 FTEs will be funded at $1.9 million with the sole purpose of performing the ICFs/MR survey function. Savings associated with the FTE reduction affecting other HCFA functions will be used to fund the pay raise which was effective in January of this year.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Question: The reauthorization for the National Center for Health Services Research expanded the role of the Center and emphasized the importance of technology assessment. It provided a source of additional funding, providing 7.5 percent to be taken from the 1 percent set-aside for departmental evaluation. I understand that 7.5 percent of the maximum set-aside could be as much as $5 million. Yet you are only providing $1.5 million. Technology assessment is recognized as playing a major role in controlling health care costs. Why aren't you encouraging as much research in this area as possible?

Answer: Technology assessment has been an important part of the research agenda of the Center, especially when the Center provides advice to the Health Care Financing Administration about coverage of new technologies under the Medicare program. In 1984 the Center spent $3.2 million in total on technology assessment and the authorization for 1986 is $3.5 million of the $16.9 million budget request. As

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to the special set-aside funding source for technology assessment, you are correct that $1.5 million will be derived from these evaluation funds. This amount represents 7.5 percent of the Department's $15 to $20 million evaluation spending plan. Although the set-aside statute permits us to utilize up to 1 percent of certain program funds for evaluation, which is estimated to be $55 to $60 million, we have never had a need to spend a full 1 percent. Our evaluation fund usage has usually been limited to less than one-third of the 1 percent limit.

HCFA RESEARCH, DEMONSTRATION AND EVALUATION

You are proposing a 33% cut in the Health Care Financing Administration's budget for Research, Demonstration and Evaluation (RD&E) activities, from $35 million in FY 1985 to $22 million in FY 1986. These RD&E efforts are directed toward developing and testing alternatives for administering the Medicare and Medicaid programs more cost effectively.

At the same time you are proposing this reduction, your budget justification acknowledges that "there is little likelihood that other organizations would carry out the necessary RD&E activities to help contain HCFA program costs."

Question. How do you justify a reduction of this magnitude in view of the serious financing problems facing the Medicare and Medicaid programs?

Answer. The Health Care Financing Administration (HCFA) will be able to perform all congressionally mandated projects and provide continuation funding for prior year commitments within the proposed $22 million in FY 1986 for Research, Demonstration and Evaluation (RD&E) activities. Since research activities are cyclical in nature, there are a sizable number of grants initiated in prior years which will not require funding from the FY 1986 appropriation. As a result, new awards can be made in FY 1986.

In addition, much of HCFA's effort over the last several years has focused on the implementation of PPS and the HMO program. Since these programs are now in place, HCFA plans to take this opportunity to shift its focus to more long-term reforms.

Finally, funds from the research budget support the design, development, and evaluation phases of a demonstration - only a small portion of the total monies spent on research projects. The services furnished to program beneficiaries under the demonstration are financed principally through Medicare trust funds and general funds as program benefit expenditures (an amount over $1 billion).

Question. What specific projects will be foregone as a result of this reduction?

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Answer. The Health Care Financing Administration (HCFA) is currently refining its FY 1985 research agenda. Since decisions have not been made concerning the current year's research plan, specific projects which would go unfunded in FY 1986 are unavailable at this time. However, it is our belief that the FY 1986 budget request is adequate to support our research priorities. HCFA will focus on long-term reforms in FY 1986 and incorporate any studies which address new initiatives in future funding requests.

PROTECTION AND ADVOCACY TECHNICAL ASSISTANCE

Last fall Congress reauthorized the Developmental Disabilities Act (P.L. 98-527). Among other things, this Act mandated that protection and advocacy groups within each State are to receive the ICF/MR survey reports and plans of corrections for deficiencies within 30 days after completion of those reports and plans. Since this is the first opportunity that these groups have had to review these documents, I believe they could benefit from Technical Assistance from the Health Care Financing Administration (HCFA) in interpreting their contents.

Question. Would you be willing to have each of the HCFA regional offices conduct a one-day technical assistance session with these groups for this purpose?

Answer. The Department would be happy to provide any assistance necessary to ensure that protection and advocacy groups are able to interpret Intermediate Care Facilities for the Mentally Retarded (ICFs/MR) survey reports and plans for corrections for deficiencies. We can arrange to have the Health Care Financing Administraion set up technical assistance sessions in each of the regions as you have suggested, or through any means amenable to these groups.

FEDERAL EMPLOYEE OCCUPATIONAL HEALTH

Question. You have proposed the deletion of all funds and support for 231 full-time equivalent employees who now staff health units at Federal agencies. The operation of the health units would be left up to the user agency. It is estimated that it will cost 40% more to run the program with contractors. Do you have results of a study which shows the savings would be realized by contracting for the services?

Answer. By eliminating the Federal employee aspect of the employee occupational health program the Federal Government would avoid the cost effect of the Federal pay scale on fringe benefits to over 231 people. The benefits savings alone are estimated to be over 25% of direct salary costs.

Question. Have you made arrangements with all of these other agencies to cover the cost of additional personnel in their own budgets?

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Answer. Since the Federal Employee Occupational Health (FEOH) program presently provides services on a reimbursable basis, funds that are presently available to agencies for contracting with the FEOH would be available to them for contracting or hiring replacement staff services.

Question. Have you told all of these other agencies that they will be running their own health units next October 1?

Answer. By the end of March, we plan to notify subscribing agencies that the 1986 budget proposes that they assume greater responsibility for operation (contract or direct) of their occupational health programs now operated by FEOH. In addition, we will advise them of the consultative and support services FEOH would be able to offer them on a reimbursable basis.

CDC - BLOOD TEST TO DETECT ANTIBODIES TO AIDS

Question. A recent report of the Office of Technology Assessment has been critical of your April 1984 announcement that a blood test for AIDS would be available within six months that would "identify AIDS victims with essentially 100 percent certainty." At that time you said that the test should prevent transfusion-related AIDS, including AIDS in hemophiliacs. The OTA report claims that the announcement "may have impeded the generation and dissemination of new information about AIDS" because it was not accurate as to the test's usefulness or availability, and that it prematurely committed the Federal Government to require use of the test in blood and plasma collections. Now that you have announced approval of the test, what is your current assessment of its value?

Answer. The tests that have been approved recently by the Food and Drug Administration are intended to screen blood supplies for the antibodies which indicate exposure to the virus that causes Acquired Immune Deficiency Syndrome (AIDS). "Positive" test results will exclude people from future blood or plasma donation and their blood from use. However, a positive result, in and of itself, does not mean that a person has AIDS. The existence of these antibodies means only that the person tested has at some time, in some way, been exposed to the virus or a related virus. The principal value of the new tests is as an additional insurance policy for our currently safe blood supply.

Although we do not encourage the use of the tests for general screening of high risk populations or as a diagnostic test for AIDS, we recognize that many concerned persons will want to be tested for exposure to AIDS. Because of this, these tests will also be available to public health and private laboratories to which physicians send blood samples for analysis. We are strongly urging that those people who want to be tested for AIDS exposure do so at these alternate locations, and not at blood banks.

OMB ROLE IN DECISIONS

Question. Can you review for us the genesis of the OMB directive that prevents NIH from funding 6,500 new and competing grants and 533 centers as mandated by Congress. Were you

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consulted by OMB before the directive was issued? If so, what was your response? If not, why not?

Response. The 5,000 level for 1985 was developed in the context of the government-wide policy of "freezing" expenditures. The proposal was discussed as one option for minimizing the need for spending increases between 1985 and 1986. The alternative would have been to substantially reduce the number of new grants or make major offsetting reductions in other research mechanisms. My staff worked with OMB in considering these options.

Question. Mr. Don Moran of OMB in a recent statement before the National Health Council said that "Congress broke a treaty with the Administration" and suggested that the increase in the grant number to 6,500 was whimsy. Madame Secretary, do you know the reasons that 5,000 was established as a floor?

Response. The 1979 report of the HHS Steering Committee for Development of a Health Research Strategy identified stabilization of the science base as the most important research planning need. The 1979 initiative was affirmed in the FY 1981 budget. In February 1980, testifying before the appropriations committee, the NIH Director expressed the Administration's desire to fund 5,000 research grants in 1981, or roughly a third of the approved applications. This strategy was initiated to smooth out the large fluctuations that occurred in the numbers of new and competing projects that could be funded each year in an effort to achieve the goal of introducing a degree of predictability to the funding of research and thereby continue to attract the nation's best scientists to this effort.

AWARD RATE - GRANTS

Question. I have here a chart that shows the number of peer-reviewed approved applications for research grants since 1975, and the number and percentage of these grants that were funded in each year. The report suggesting the floor of 5,000 was written 1979 when NIH approved 11,510 and funded 5,944 grants, or 52%. In 1984 when we were considering the 1985 budget, NIH estimated that 16,142 grants would be approved. A funding level of 5,000 would provide 31% of approved grants with funding. Do you believe that funding less than one-third of grants judged as good and necessary research is good public policy for a Department and a Congress charged with providing for the public welfare. 6,500 grants would provide a 40% level of funding. Is 40% funding of necessary research good public policy?

Response. The need for stabilization of the research base was first raised in 1978 as the Department embarked on the process of preparing a long-range health research plan. The number of awards that year was 5,200. The need for stabilization was raised in response to the large fluctuations that occurred in the numbers of new and competing projects in the 1970's. For instance; the number of new and competing grants rose from 2,592 in 1973 to 4,540 in 1974, and dropped to

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3,464 in 1976 and 3,840 in 1977. This fluctuation occurred as a result of the three-year average project period. In each fiscal year, the continuing commitments are met first, and applicants for renewal of expiring grants must compete with new applicants for the remaining funds. The policy begun in 1981 to fund 5,000 new and competing grants, or about one-third of the approved applications, has been successful in reducing this fluctuation. Stabilization of research project grants at 5,000 new and competing projects has been and continues to be good public policy.

PROPOSED FTE REDUCTIONS AT NIH

Question: Again this year you are proposing to reduce full-time equivalents (FTEs) at the National Institutes of Health, despite the fact that Congress has provided increased funds over the past few years allowing for real growth in both intra and extramural programs.

How do you expect NIH to both maintain its intramural research program and to exercise proper oversight of its extramural?

Answer: The proposed reductions in FTE ceilings at the NIH will be achieved through a combination of actions such as eliminating the summer program, continuing to review selected functions/services for possible contracting out or increased productivity, organizational restructuring, and putting in place selected hiring restrictions. We will make every effort to minimize the impact on the NIH intramural programs and the ability to manage the extramural program.

Question: I understand that the FTE reduction has caused a real staffing problem at the Clinical Center. How has this FTE problem affected patient care?

Answer: The Clinical Center was given special consideration in the allocation of the FTE ceiling. To accommodate the reductions, the Clinical Center is exploring a variety of ways to improve productivity within the hospital. This includes limited contracting for services now provided by the Clinical Center employees. The Secretary has directed that priority recruitment be given to positions involving direct patient care; and thus the hospital will continue providing safe, high-quality care.

Question: How has it affected funded intramural research protocols?

Answer: As stated above, we will continue to make every effort to minimize the impact of the FTE reductions on the intramural research program.

PHYSICIAN COMPARABILITY ALLOWANCES

Question: I understand that OME is interfering with the Physician Comparability Allowance at the NIH Clinical Center. Has this caused the loss of hiring of new physician researchers and/or the loss of present physician researchers? Please provide for the record a description and history of the comparability allowance and why the Administration believes it is no longer necessary. Be sure that the "physician researcher" is addressed in your response.

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Answer: The Office of Management and Budget has approved the Department's regulations on Physician Comparability Allowance. There is no longer a problem in this regard.

PROPOSED HEALTH SCIENCES BOARD

Question: The Institute of Medicine Committee recommended the establishment within the Department of Health and Human Services of a Health Sciences Board "to oversee the health research organization, missions, priorities, and institutional management of the several elements of the Public Health Service..." Do you feel such a board would be effective?

Answer: The Department does not believe the proposed Board would be effective and is opposed to its establishment. It would create an additional bureaucratic layer and establish yet more administrative superstructures to be imposed upon current practices before first determining that such current practices cannot deal with or could not be strengthened to deal with contemporary issues. This proposal would impose a significant set of additional relationships at the interface between biomedical research and congressional oversight, would further compound complex issues, and would contribute to the management burden of the PHS and all agencies. Specific concerns are as follows:

- The proposal implies that the Assistant Secretary for Health and the PHS agency heads, acting collectively, are not adequately addressing cross-cutting concerns and organizational issues that fall at the boundary of the respective agencies. Not only is there no evidence to suggest that this is the case, but also no indication that any serious analysis of the issue was conducted.

- This proposal does not fully recognize the direct and continuing role played by Congress in the oversight of the PHS.

- It is doubtful that such a Board could conceivably perform the functions suggested for a single, complex agency, let alone the entire PHS. Increasing membership on the Board would not address the concern.

- It would be highly unusual for any continuing advisory body in PHS to have its own staff, budget authority, and resources to establish groups and panels and to commission studies. Such a body may not remain advisory; it could easily become another operating body in the management structure and in conflict with the responsibilities and authorities of the Assistant Secretary for Health and agency heads.

- Such a Board would be costly and create yet another administrative, bureaucratic function at a time when administrative costs are being limited by Congress and reduced by the Executive Branch.

- To implement this recommendation would require additional administrative positions at a time when full-time equivalent position ceilings are being reduced.

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- The comparison of this Board to a board of regents of a university does not fully recognize the differences between a university and a Government agency.

Question: Regarding the creation of a new Institute at NIH, the IOM Committee recommended a presumption against creating new Institutes unless a set of criteria were met. Do you feel there is a need for the creation of any new Institutes at NIH at this time?

Answer: The IOM report states that NIH has reached a point at which there should be a presumption--to be overridden only in exceptional circumstances--against additions at the Institute level, whether they are proposed to occur by fission or by transfer from outside NIH. Although a particular research area may benefit from the establishment of a new Institute, the overall manageability of NIH suffers from the cumulative effect of such additions. This is because new Institutes 1) fragment the scientific effort and diminish effective communication with key scientists in other Institutes; 2) add to the burden and difficulty of effective program coordination by the NIH Director and his staff; and 3) add to administrative costs without ensuring increased appropriations.

The Department fully endorses this view and does not believe there is a need at this time for the creation of any new Institutes at the NIH.

Question: The Institute of Medicine Study Committee that was convened to review the organizational structure of the NIH recommended strengthening the NIH Director's Advisory Committee by converting it to a more independent NIH policy and planning council "to provide for the Director a continuous evaluation of the research mission and function of NIH, and to advise the Director in the formulation of long-term plans and in setting research priorities." What is your reaction to proposing greater independence for the Committee that is designed to assist the Director of NIH in fulfilling his mission?

Answer: The Department views the creation of an autonomous body of advisors, with its own staff and budget, with freedom to define its own agenda, and without the responsibility and accountability characteristics that accompany Federal employment, as unsound public administration.

When one looks at the history of the Advisory Committee to the Director, NIH (DAC), its evolution and changing role over time, and the extent to which it supports the Agency in the policy development process (none of which was addressed in the report), it becomes clear that the Committee has developed in ways that have strengthened the NIH Director's ability to manage the Agency, to deal with cross-cutting areas of concern, and to engage in broad policy development activities. To alter the role of the DAC to an independent body at a time when it is evolving into an effective unit would not only be counterproductive but also likely to weaken, rather than strengthen, the NIH Director's ability to manage the Agency.

Question: Do you agree with the IOM's belief that such independence will help make the committee more effective in fulfilling its responsibilities?

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Answer: The Department does not agree with the view that an independent advisory committee to the Director, NIH, will be more effective in carrying out its reponsibilities. At the time of the establishment of the DAC, the NIH held that experience with the use of an inter-council group of this nature in the discharge of the Director's function would provide useful insight into the need for further evolution of this or some other advisory arrangement. With changes recently made by the current NIH Director in the operation of the DAC, it is the Department's firm belief that the DAC has evolved into an effectively functioning body and that its role in supporting the NIH is not, at this time, in need of significant alteration. The NIH will continue, as it has in the past, to examine the role of the DAC and make improvements designed to enhance its effectiveness.

Question: What is your reaction to the recommendation that the Director of NIH be given greater budgetary authority, including a 1.0 percent discretionary fund to seed selected areas of research in the existing Institutes, as well as a limited authority to transfer up to 0.5 percent of the NIH budget across Institute lines in the case of a public health emergency?

Answer: The NIH finds merit in the report's suggestion that some discretionary funds should be available to the Director. However, the discretionary fund should provide sufficient resources to address both emerging crosscutting research opportunities and the need to meet public health emergencies. That is, the presence of the discretionary fund so constructed would preclude the need for the proposed budget transfer authority, which would prove disruptive.

Question: In the absence of such authority, how have public health emergencies been handled in the past, such as in the case of Acquired Immunodeficiency Syndrome (AIDS)?

Answer: In the past, structural constraints have not seriously impeded the ability of the NIH to respond to special research opportunities or public health emergencies. As the history of AIDS funding shows, however, much could have been saved in terms of administrative and program efficiency if it had not been necessary to go through a supplemental appropriation process.

OVERALL DEPARTMENT MANAGEMENT

Question. I understand that transfers from the Medicare trust funds to Department accounts are made to offset Medicare-related administrative costs.

Excluding the Health Care Financing Administration (HCFA) and the Social Security Administration, the transfers have increased from $30 million in fiscal 1984 to $68 million for fiscal 1986. That's more than double!

Why such a tremendous increase in less than three years?

Answer. The transfers you are referring to include transfers not only from the Medicare trust fund but from the Social Security trust funds as well. In addition, the $38 million increase which you cite includes an increase of about $12 million related to the Indian Health Service which is

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not a transfer to support administrative services. Rather, it is a reimbursement from the Medicare trust fund for health care services provided to Medicare beneficiaries at Indian Health Care facilities.

The actual increase in trust fund transfers for administrative costs, excluding HCFA and SSA, between FY 1984 and FY 1986 is $26 million. The major component of the increase, $24 million, is for the Office of the Inspector General. The increase in trust fund support for the Office of the Inspector General was made in order to more accurately reflect the actual allocation of resources among program activities. The Office of Inspector General has increased its focus on fraud and abuse activities related to the Medicare program, an area where there is the greatest potential return for the investment. Based on a workload analysis, it was determined that the current allocation most acurately depicts the true distribution of resources by program area.

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH - STAFFING

Question. In the 1984 report of the Subcommittee on Labor, HHS, Education and Related Agencies of the Senate Committee on Appropriations, the Committee stated its intention that NCHSR's position level be maintained. The exact Committee language is: "The Committee believes that the efforts of the National Center for Health Services Research are very much in the long term interest of the Department and, accordingly, wants the current position level to be maintained in order for the Center to meet its objectives." What has been your FTE level in the years that followed — FY 1983, 1984, and 1985? What is proposed for FY 1986?

Answer. The number of full-time equivalent staffyears (FTEs) devoted to the National Center for Health Services Research (NCHSR) is 154 FTE in 1983, 154 FTE in 1984, 148 FTE in 1985, and 141 FTE proposed for 1986.

Question. You appear to be allocating position reductions to NCHSR on the same basis as used to reduce administrative management positions in that portion of the Public Health Service Management Account. Why do you continue to disregard the intent of the Committee?

Answer. The staffing reduction of 7 FTE from 1985 proposed for NCHSR is part of the government-wide effort to reduce overall Federal civilian employment, and can be accomplished primarily through attrition and administrative initiatives to improve operational efficiencies. This minor reduction is not expected to impair the agency's abilities in any measurable way.

FUTURE FOR HRSA

Question. Madam Secretary, your budget proposal for the Health Resources and Services Administration calls for the elimination of health professions training—some $112.5 million worth of appropriated programs. Not counting funding for Maternal and Child Health, community health centers and related

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primary care programs, $130 million is left for all of HRSA out of $1.5 billion last year. In addition, it is my understanding that, although we don't fund it from our subcommittee, the Indian Health Service will be split off from HRSA to become a separate agency. What are your plans for the future of HRSA?

Answer. As you indicate, the 1985 Health Resources and Services Administration (HRSA) budget amounts to approximately $2.5 billion, including the Indian Health Service. The budget proposals for 1986 assume no organizational changes.

ADVANCED NURSE TRAINING

Question. In your May 1984 Fourth Report to Congress on Health Professions Manpower, you agreed with the Institute of Medicine study that there was a continuing need for advanced Nurse Training. How do you now justify eliminating Nurse Training Act funding?

Answer. Based on the 1984 Status of Health Personnel in the United States, fourth report, we are estimating a supply of 1,780,000 total nurses will be available nationally by 1990. It is our understanding that personnel levels of this magnitude will approach or exceed the national demand. We based our budget recommendations on the national estimates of nurse graduates and resulting availabilities. However, some specialized areas of nursing may not have surpluses.

HRSA FTE

Question. Under your proposed budget for the Health Resources and Services Administration, you would have to conduct a rather large RIF--about one out of two people employed at HRSA--shortly after the beginning of the new fiscal year. How had you intended to pay severance and other costs related to a major reduction in force when you have not requested any funds for the termination account?

Answer. We recognize that there are several legislative proposals effecting program eliminations in HRSA. These will ultimately result in staff reductions. However, we have not incorporated a request for severance costs in the budget because of the uncertainties as to the exact number of people that would actually be separated unwillingly from Federal employment. The major reduction in force (RIF) implemented last year in the Office of the Secretary was accomplished without any employees being separated. Combining a strong outplacement program, offering early-out retirement and essentially freezing all replacement hiring to maximize the effect of attrition, we avoided incurring any severance or severance related pay costs. We would attempt to effect necessary staff reductions in HRSA in a similar fashion. Failing a complete success, we would then consider sources of additional funding for severance pay and related costs as the magnitude of the need became clear.

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Question. How did you determine the number of employees who should leave, in relation to your proposed program cuts?

Answer. Essentially, all staff managing or administering specific programs proposed for elimination plus a pro-rate share of policy and operational support staff associated with the closing programs were earmarked as unnecessary. The determinations were made in a level of effort rather than specific position by position review.

MATERNAL AND CHILD HEALTH

Question. The Department's budget request for the Maternal and Child Health straightlines the setaside for programs of regional or national significance--but at the 1984 level--which would mean about an $11 million drop from the figure appropriate in 1985. Programs funded through this setaside have been highly commended for reducing infant mortality rates, the incidence of handicapping conditions among children and, in general, for improving the health of babies born to high risk mothers. Why are you proposing this reduction at this time?

Answer. Freezing the total amount of funding withheld in the so-called 15% Federal setaside allows us to distribute to the States, an increased amount of funding into the primary purpose of the program - provision of essential health care services to mothers and children. If significant future gains are going to occur in reducing infant mortality rates, the State Maternal and Child Health clinics will be where a large part of the workload is accomplished. Allowing increased States allotments, albeit small, is one of many responses to the pressing infant mortality problem.

PROGRAM TERMINATIONS

Question. The Department's own grants manual outlines a procedure for covering grants already in the pipeline. In the case of Area Health Education Centers (AHEC's), for instance, it appears that a phase out period would be required due to the fact that commitments were entered into with Universities for a stipulated period of time--say, three years. Your request for a total cutoff of funding, therefore, appears to be contrary to your own Department's guidelines. Were your budget proposal to be enacted, what is your thought as to how those programs with multi-year commitments should be handled?

Answer. The Public Health Service (PHS) Grants Policy Manual, which by reference is a part of all grant awards made by the PHS, stipulates that "the approval of a project period that extends beyond the budget period for which funds are provided expresses the PHS intention to provide continued financial support to the project. However, the recommended levels of future support within a project period are not guaranteed by

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PHS...and creates no legal obligation to provide such future support." Therefore, if funds are not appropriate for the program, the Department is under no obligation, legal or implied, to make future grant awards.

PRIMARY CARE BLOCK GRANT PROPOSAL

Question. Madam Secretary, while you are again proposing to merge Community Health Centers, Black Lung Clinics, Migrant Health Centers and Family Planning programs into a Primary Care Block Grant, I am not as much disturbed by that because I am sure it will be rejected again--as I am disturbed by your budget request for funding. It appears that you have requested a straight line amount--$550.1 million--the same as the 1985 appropriation. However, since we moved $15 million from the National Health Service Corps to the Community Health Centers to help pay for Corps assignees, the 1986 request would be a $15 million net reduction. Were your proposals to be enacted, what programs do you have in mind to take a reduction in order to meet the shortfall?

Answer. If the proposal to merge Community Health Centers, Black Lung Clinics, Migrant Health Centers and Family Planning programs into a Primary Care Block Grant is enacted, numerous administrative and operational benefits would accrue to the new program. Flexibility to target resources, thereby enabling States to be more responsive to their primary care needs; and streamlining of Federal administration would combine to produce economies on both the State and Federal levels. It is unclear that any sub-program would experience a shortfall under the proposed mode of operation, but should this occur the individual States administering the program would be responsible for determining the necessary reaction.

AIDS

Question. We are receiving conflicting reports about Departmental Expenditures for Fiscal 1985 on the treatment, research, data collection and education for Acquired Immune Deficiency Syndrome.

The Department's Budget Office indicates that you plan to spend $96 million for this purpose in FY 1985.

Please provide a detailed report on how and where the money will be spent.

Answer. The following table displays the FY 1985 PHS Obligation Plan for Acquired Immune Deficiency Syndrome:

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	FDA	CDC	ADAMHA	NIH	PHS
		(dollars in thousands)			
1. Etiologic Agent and Co factors: Confirmation and extension of observations on causative agent and discovery of role of co-infections and co-factors.....	$---	$ 3,210	$ 685	$ 8,783	$12,678
2. Development and Evaluation of Blood Tests:					
a. Development.....	---	980	---	1,050	2,030
b. Evaluation.....	2,970	1,282	---	435	4,987
3. Surveillance.....	---	4,335	---	60	4,395
4. Epidemiological Studies (to Determine Natural History of AIDS).....	---	4,068	648	21,295	26,011
5. Development and Evaluation of Vaccine (including Animal Model).....	4,010	516	---	6,072	11,248
6. Studies of Therapeutic Intervention:					
a. AIDS.....	895	---	---	6,622	7,517
b. Opportunistic Infections.....	---	186	---	5,184	5,370
7. Immunologic Studies.....	---	32	---	8,620	8,652
8. Psychosocial Factors.....	---	---	1,479	129	1,608
9. Simian AIDS.....	---	---	---	2,078	2,078
10. Prevention of Transfusion-related AIDS.....	---	707	---	218	925
11. Bioethics and Biosafety.....	---	124	---	46	170
12. Information Dissemination/ Public Affairs.....	---	3,260	---	669	3,929
13. Facilities Construction.....	950	4,500	---	---	---
PHS TOTAL.....	$8,825	$23,200	$2,812	$61,261	$96,098

Question: How much of the $96 million is available to the Department by direct appropriation and how much by the shifting or reprogramming of funds? Please include in your report the programs from which these funds were derived and the impact the loss of funds had upon these programs.

Answer: The entire $96 million estimate for AIDS in FY 1985 is available by direct appropriations.

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Question: Please provide the Committee with a detailed analysis of the funds requested for AIDS in FY 1986 and how the Department plans to respond to any new findings that may require additional funds.

Answer: The table below displays the FY 1986 estimates requirements for Acquired Immune Deficeincy Syndrome requested in the FY 1986 budget:

FDA	$ 3,725
CDC	18,700
NIH:	
National Cancer Institute	23,851
National Heart, Lung, and Blood Institute	11,200
National Institute of Dental Research	37
National Institute of Neurological and Communicative Disorders and Stroke	1,100
National Institute of Allergy and Infectious Diseases	22,337
National Eye Institute	60
Divison of Research Resources	1,731
Subtotal, NIH	$60,316
ADAMHA	2,823
Total Public Health Service	$85,564

If additional AIDS resource requirements are identified, the Department will request additional resources from Congress through the appropriate mechanism including reprogramming, supplementals, or budget amendments.

RESEARCH AND DEVELOPMENT FUNDING

Question. The Administration has increased its spending on research and development funding by 56% over the FY 1981 level. In FY 1986, they are planning to spend almost $53 billion. Seventy percent of the R&D budget is for defense and constitutes a 102% increase over FY 1981 levels. Thirty percent of the R&D budget is for so-called civilian R&D, an increase of 2% over the FY 1981 budget, or if adjusted for inflation, a 15% decrease.

o Madam Secretary, as a member of the President's Cabinet and the chief proponent for social and health programs, how much input did you have into this R&D budgetary decision?

Answer. It is my responsibility to advise the President on research funding levels for research in biomedicine, substance abuse, mental health and in several areas of social and behavioral research. Fully 95% of the FY 86 research budget request for this Department consists of funding for the National Institutes of Health and the research programs of the Alcohol, Drug Abuse and Mental Health Administration. Proposed FY 1986 funding for research in these areas is up 1.3 billion or 38% over the FY 1981 budget. The President's

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budget clearly reflects the strong commitment to these important areas of research related to the nation's health that both he and I share.

FY 1986 RESEARCH FUNDING

Question. Given your knowledge of Presidential priorities, how would you like to see this budget changed?

Answer. The FY 1986 budget provides the funds necessary to a stable and productive biomedical research effort. I support it and look forward to the important benefits that will be realized from this essential investment.

Question. According to my calculations, the amount available for discretionary programs for the Department in the fiscal year 1986 budget you proposed will be $2.4 billion less than the 1985 appropriation. Do you believe this points us in the right direction toward the goal of meeting human needs?

Answer. With the deficit reaching alarming proportions, tough decisions had to be made in preparing the fiscal year 1986 budget. Unless we begin to reduce the deficit and move toward a balanced budget, human needs will not be adequately met in future years.

Funds for discretionary programs are 4 percent of the total HHS budget for 1986, the same level as in 1985 and 1 percent lower than was appropriated in 1984.

To achieve the $2.4 billion of reduction, we have proposed elimination of two programs - Work Incentives ($.3 billion) and Community Services Block Grant ($.4 billion). The Work Incentives program would be replaced by the proposed work opportunities program for AFDC recipients in the Assistance Payments appropriation. Programs currently funded by the Community Services Block Grant would be funded at the States' discretion under the Social Services Block Grant. Under this proposal each of these program areas would be funded as entitlements in 1986.

In addition, a legislative proposal to be transmitted later, will recommend alternative funding for the Low Income Home Energy Assistance Program. Oil overcharge collections will reduce the funding of that program from general revenues by $.8 billion without reducing the program level of $2.1 billion.

The level of new and competing grants at NIH will be stabilized at 5,000. This proposal will save another $.3 billion. Elimination of health professions and health planning programs will net another $.3 billion. Other reductions include adjustments for the refugee flow ($.1 billion) and modernization and repair of only high priority Indian Health Facilities projects ($.1 billion).

These reductions will still enable HHS to perform it's essential role in meeting the human needs of Americans.

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HEALTH PROFESSIONS TRAINING

Question. It is my understanding that we are all working to help reduce health care costs. It is also my understanding that you embrace the philosophy that competition makes everything less expensive -- and that when supply meets demand, everyone gets more competitive. Yet you seem to believe that this is not the case when it comes to health professions training.

What specific evidence do you have that the numbers and kinds of health care professionals have increased so much that it is no longer necessary to expend one nickel to aid in encouraging their training?

Answer. In the early 1960s when the Health Professions Education Assistance Act was passed to deal with the perceived shortages of physicians and other health professionals, the capacity of the educational system was seen as the major constraint to producing adequate numbers of practitioners for the future. Historically, many more individuals have wanted to enter the health professions than have been able to gain admission to educational programs preparing them for health careers. Consequently, the legislation focused on increasing both the numbers and capacity of health professions education institutions. As a result, for example, the number of allopathic and osteopathic medical schools increased from 92 in 1960 to 142 in 1984, and the number of medical students increased from 32,232 to 73,265. The number of dental schools and dental students similarly increased significantly, rising from 47 to 60 and from 13,580 to 21,428, respectively, over the same period.

Question. According to your view, if we have fewer doctors and nurses, won't the cost of health care increase?

Answer. A variety of factors have contributed to the rising cost of health care over the past two decades. Today, however, we are witnessing changes in the major causes of health care cost inflation. First, the tide is turning against cost-based financing and unconstrained demand as both the public and private sectors experiment with payment initiatives that provide incentives for cost-saving behavior among producers and consumers of health care. The numbers of practitioners in most of the health professions, we believe, have reached high enough levels to precipitate more competitive behavior. Discontinuance of Federal aid to health professions education will not immediately affect the growth in the numbers of health professionals.

GOVERNMENT RESEARCH FUNDING

Question. In 1986 the Administration proposes to spend $58 billion government-wide on research and development. Of this amount 68 percent ($40 billion) is for military purposes and 8 percent ($4.8 billion) is for health. As Secretary for Health and Human Services, having a major responsibility for federal support of biomedical research in the United States, do you agree with the eight to one imbalance in favor of defense?

Response. Defense research is very different from the kind of research supported by this Department, and comparisons

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between the two cannot be easily made. We believe that the $4.8 billion requested for biomedical research is sufficient to sustain the momentum of the health research establishment. At this level, we will continue to see remarkable advances in the underlying mechanisms of health and disease and in the practice of medicine.

NIH OVERALL BUDGET

Question. The Administration is proposing a $4.8 billion budget for NIH for FY 1986. This is a $300 million cut from FY 1985 levels. What areas of research are you proposing be cut back? Can you honestly tell the Subcommittee that health research needs have declined?

Response. The FY 1986 budget for NIH is essentially a "freeze" budget. In fact, examined from a program level perspective the request represents close to a 2 percent increase over 1985. About two-thirds of the dollar reduction was made possible by forward-funding the continuation costs of a number of grants begun in 1985. These projects will be active in 1986, but will not require additional funds. Other reductions are principally in salaries and expenses and administrative support categories.

SUPPLY AND DISTRIBUTION OF NURSES AND DOCTORS

Question. Your testimony last year, particularly in response to Senator Andrews' questions, indicated that you we in possession of data which revealed that there is a surplus of doctors and nurses, but a poor distribution of them. You also indicated that your efforts were geared toward training in the specialities in which there is not a surplus such as geriatrics.

Senator Andrews asked what initiatives you were moving ahead on to help those areas deficient in their supply of health care providers. You said you thought he had a good point . . . that perhaps we ought to look at what we could do to help to get some of those people we are training to locate in underserved areas in order to alleviate the geographic distribution problem.

You submitted for the record a list of some programs for nurse training which are being conducted at North Dakota colleges and universities. You stated that "more than one-third of the 60 nursing special projects currently focus on enhancing the nursing services in rural areas." You also stated that "in addition, all of the area Health Education Centers (AHEC) program grantees work to increase the numbers and the training level of nurses in remote areas."

I applauded. While we can debate whether or not there is a shortage of nurses or doctors, we did agree that the distribution problem is a serious one. And your description of ongoing programs made me believe we were perhaps on the right track to resolving the problem.

And, looking at the budget request for this year, I see that I was correct in being optimistic. You managed to resolve the entire distribution problem in one short year. Now, to my

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question. Am I correct in this assumption, since you are requesting not one red cent for any of these programs you trumpeted just last year?

Answer. Although there may be some continuing shortages of physicians and nurses in particular areas of the country, the nation as a whole is facing a future surplus, not shortage of physicians and nurses. In 1970, there were 323,000 physicians and 9,446 medical school graduates. For 1983, the most recent year for which we have completed data, these numbers have grown to 497,000 physicians and 17,119 graduates. Our projections are that by 1990 the number of physicians will grow to 595,000 assuming the current level of output from medical schools. These trends exist across the entire spectrum of health professions occupations. We feel it is time for the Federal government to end the "priming of the pump" with the large gains in personnel.

Obviously since last year, all the problem of shortages in specific rural areas have not be solved. What has occurred is the overwhelming need to reduce the large - $230 billion - Federal budget deficit. Choices must be made and spending lines must drawn. In the health professions education area, we felt the Federal government has made a substantial investment over the past 20 years in building training capacity and the time was right for withdrawing Federal subsidies.

ICF/MR REGULATIONS

Question. Madame Secretary, the last two times you have testified before this Subcommittee I have asked you when the new regulations for the ICF/MR program would be issued. The first time you stated your intention to issue the proposed regulations in fiscal year 1985, and the second time you stated that you could not predict when the regulations would be out. Yesterday I received a letter from you stating that the regulations have "entered the Departmental clearance process." By what date will you issue these regulations?

Answer. The proposed regulations for the ICF/MR program are now under review in the Department. These standards have been carefully developed to increase the focus on active treatment of the client, to reduce paperwork and eliminate duplicative requirements and to maintain essential client protections. We expect the regulations to be issued shortly, however, we want to make every effort to ensure that they adequately reflect the needs of clients and meet other program considerations.

COMMUNITY HEALTH CENTERS

Question. Madame Secretary, as you may recall, on the 20th of February I directed a letter to you outlining my deep concerns regarding the well being of Community Health Centers.

Dollar awards for the centers have been falling in spite of increased appropriations and in spite of Congress' specific pleas to

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the Department to give highest priority to maintaining current service levels at existing centers.

In addition, the Department's plans to use $52 million of the amount appropriated for fiscal year 1985 -- which only increased $9 million over the 1984 appropriation -- for new centers, clearly is contrary to the intent of Congress. The Department has also decided to declare 97 percent of the centers potentially ineligible for funding because they failed to meet yet another set of different criteria.

How, in your view, do these actions serve to improve health care to the nation's poorest, most disadvantaged people?

Answer. As I explained in my response to your letter of February 20, the Federal Register notice referring to $52 million in new funds was actually comprised of three parts, only $9 million of which was truly "new" money under Section 330. $25 million represents the maximum needed for reprogramming from the National Health Service Corps (NHSC) appropriation to place 700 NHSC personnel in Community Health Centers (CHCs) -- $15 million already has been reprogrammed. $4 million is Migrant Health funds -- the $2.6 million increase plus $1.4 million already available for special activities. Finally, $14 million is composed of funds allocated for CHC special activities, one-time supplementals and health services for the unemployed, which will be used to strengthen operations at existing centers.

Question. Why have you not honored Congress' directive to maintain current service on funding levels at existing centers?

Answer. The Bureau of Health Care Delivery and Assistance (BHCDA) of HRSA annually reviews each of the approximately 600 continuation grant applications submitted by CHCs to assure that adequate funds are provided to maintain existing health services while critically reviewing each health center's base grant level to assure that funds are spent only in the most efficient and effective manner possible. BHCDA conducts such reviews based on a standard series of funding criteria, including such issues as individual health center performance on financial and administrative indicators as well as a continual review of the relative need of the population served by the health center. These individual health center reviews have been and, we expect, will be the most appropriate mechanism to assure that health centers receive appropriate funding levels, while allowing BHCDA the management capability to utilize funds in the most prudent and cost effective manner. This process, which has been used for over 10 years, results in projects receiving increased funding level or decreased funding based solely on their need and performance.

HEALTH PROFESSIONS TRAINING

Question. It is estimated that America's population of 75 and older will increase over 50% by the year 2000. Recognizing this, Congress appropriate $5 million for geriatric training. You are proposing to eliminate the funding in FY 1986. Do you feel we have an oversupply of geriatric specialists, thus making this training unnecessary?

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Answer. When facing an estimated budget deficit in 1986 of $230 billion if all programs funded in 1985 are continued into 1986, difficult choices had to be made. We do not feel that an oversupply of geriatric specialists exists, nor do we project an oversupply in the near future if the immediate past is an accurate indicator. However, in light of our projections of significant surpluses in total physicians and nurses combined with an anticipated free market response on the part of highly educated health professionals to seek out the expanding areas of health care needs, we chose our concern for the mounting deficits as a higher priority than continued funding of this specific program.

Question. Were the needs of the elderly for geriatric specialists considered when your funding was recommended for HP training?

Answer: We addressed the needs of all the people with primary concern for those people least able to provide for themselves when making all funding decisions in our budget proposals.

PROPOSED FREEZE IN MEDICARE PROSPECTIVE PAYMENT RATES

Question. Your FY 1986 budget proposes a freeze in reimbursement rates for hospitals at the FY 1985 level, for an estimated savings of $1.8 billion next year. What impact do you anticipate the freeze would have on beneficiaries, in terms of access to services and quality of care?

Answer. We do not believe the propose freeze on the prospective payment rates will have any adverse impact on beneficiaries. The recent productivity gains experienced by the hospital industry should enable hospitals to accommodate a one-year freeze in the rates without reducing either access to services or quality of care.

Question. How do you propose to monitor the impact of the freeze?

Answer. We will continue to monitor quality of care under the prospective payment system very closely through the Peer Review Organizations (PROs). The PROs, which are responsible for the review of Medicare admissions nationwide, are focusing their reviews on such quality indicators as the appropriateness of admissions, transfers, outliers and readmissions within seven days.

Question. What evidence do you have to suggest that hospitals would be able to absorb the freeze in payment rates without shifting costs to other payors?

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Answer. Hospitals have recorded productivity gains across the board. Length-of-stay, for example, declined 10%, from an average of 10 days in 1983 to 9 days in 1984. AHA data indicates that there have been significant reductions in full-time equivalent personnel and total inpatient expenses. In addition, industry publications suggest that in the first year of PPS, most hospitals increased their profit margins, especially major teaching hospitals. Moreover, other third party payers are becoming more aggressive in constraining health care costs. Therefore, we do not expect hospitals to shift costs to other payers.

GAO STUDY OF PROSPECTIVE PAYMENT SYSTEM

Question. Madame Secretary, a preliminary report by GAO indicates that the Medicare Prospective Payment System may be forcing patients out of the hospital too soon and in poorer health than before the system was instituted.

How do you respond to this finding, and wouldn't your proposed provider freeze risk eroding the quality of care by increasing the incentive to discharge patients earlier?

Answer. A recent preliminary report released by the GAO indicates that patients are being released from the hospital sooner under PPS and as a result may require skilled nursing or home health care. As you know, this report is still preliminary and we will be reviewing it very carefully. We do not yet have any conclusive evidence that is in fact occuring to a great degree, however, HCFA will be monitoring this situation very closely. The Peer Review Organizations are reviewing hospital admissions and transfers to other facilities and are a key element in efforts to analyze the impact of PPS. In addition, Medicare Contractors have intensified their audit activities with respect to outpatient, skilled nursing care, and home health services.

We do not believe that the proposed freeze on the prospective payment rates will result in an erosion of quality of care. The recent productivity gains experienced by the hospital industry, in such areas as length-of-stay and employment, will enable hospitals to adapt to this one-year freeze. Moreover, as I mentioned previously, the Peer Review Organizations will be monitoring this situation very carefully.

Head Start

Question: You are proposing a funding freeze for Head Start at $1,075,059,000. How do you expect Head Start grantees to avoid cutbacks in children being served due to the impact of inflation?

Answer. We have had prior experience with level budgets. In Fiscal Year 1983, the budget was almost identical to that of Fiscal Year 1982. We were able to maintain both enrollment and service quality at the Fiscal Year 1982 levels through efforts similar to those to be used in Fiscal Year 1986.

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In Fiscal Year 1986, the Head Start Program expects to maintain its Fiscal Year 1985 enrollment of 448,250 by working with our grantees to assure that all Head Start programs are making maximum use of their resources. We will conduct cost reviews of at least 1/3 of our 1,280 grantees using a recently developed instrument which will assist us and the grantees to identify areas of potential efficiencies. We will also, when reviewing grantee refunding proposals, assist those programs not receiving a cost review to achieve whatever cost efficiencies might be possible. The Head Start program will also continue to work with our grantees to assist them in securing alternative resources so that Head Start dollars continue to be used only for those costs that cannot be paid from other sources such as Medicaid, local government agencies, etc.

Question. Isn't it true that less than 20 percent of eligible children now receive services?

Answer. Our data indicates that about 20.3 percent of the eligible population currently receives Head Start services. We estimate that this will increase by approximately one-half of a percent by the end of this year after we have enrolled 14,000 additional children.

Question. What do your evaluations reveal about the cost-effectiveness of the Head Start program?

Answer. The current cost per child in Head Start is $2335 per year. When one considers that Head Start is a comprehensive pre-school program providing services in the areas of health, nutrition, education, social services, and parent involvement, we consider this to be a most reasonable cost.

In addition to the significant health, cognitive and socio-emotional developmental growth children experience while in Head Start, there is also growing research evidence that Head Start children adapt better to their elementary school environment that non-Head Start children from comparable family backgrounds. Several longitudinal studies have shown that Head Start children are less likely to be retained in grade, assigned to special education classes, or drop out of school.

These positive social indicators of success for Head Start children after they leave the program can readily be translated into major cost savings for the economy and savings that exceed the cost of putting a child through a Head Start program.

Families and communities also benefit from Head Start, as evidenced by increases in the economic base of many Head Start families and by improvements in health, social service and education institutional effectiveness and efficiency which can be attributed directly to Head Start contributions and influence.

CENTER FOR NURSING RESEARCH

Question. On January 14 of this year, you announced the creation, administratively, of a Center for Nursing Research in the Public Health Service "to take charge of departmental

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studies and research grants on nursing, including such topics as the nursing needs of the chronically ill, disabled or dying, and ethical guidelines for nursing services." You even named someone to be in charge of this Center for Nursing Research.

Then we get your budget and notice that out of the $66.7 million appropriated for nursing programs, zero is proposed for 1986. What will the head of the nursing division do, with no programs to be in charge?

Answer. Should Congress agree with the 1986 budget request as proposed, the need for a Center for Nursing Research would be eliminated.

Question. Why would you bother to create a center that has no programs or people in it?

Answer. This Department is resonsible for administering a significant program - $9.4 million - of extramural nursing research projects designed to enlarge the body of scientific knowledge that underlies nursing practice, nursing services administration, and nursing education. As long as this responsibility exists, we felt an organizational focal point would be helpful in fostering quality research.

DIVERSION OF ADMINISTRATIVE FUNDS

Question: Last year, Congress added $63 million in the regular fiscal 1985 Labor-HHS-Education bill to restore 2,850 personnel of the Social Security Administration which the President's budget had proposed be eliminated through attrition. We now understand that this money is being diverted to finance the Federal pay raise which went into effect January 1, 1985. Did you approve this maneuver, which appears to subvert the intent of the Budget Impoundment and Control Act by denying Congress the opportunity to act on a rescission request?

Answer: The Social Security Administration did not need the money for additional personnel. Backlogs are down, processing times have improved and in a number of areas workloads have come in below budget. There has been no intent to mislead the Committee; the use of the $63 million for other payroll costs was prominently featured in the budget justification prepared by SSA (page 204).

Question: In many other places in the budget, the Administration is requesting supplementals to finance the recent Federal pay raise, and simultaneously proposing offsetting rescissions--so what is the rationale for treating the Social Security budget differently?

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Answer: As stated SSA has experienced workloads below budget and established staffing levels accordingly. As a result, SSA is able to absorb the cost of the Federal pay raise within the appropriated amount for FY 1985.

Question: You appear to leave us no alternative but to legislate staffing levels directly in the appropriations bill. Wouldn't it be better for you to honor Appropriations Committee report language directives on staffing levels, instead of forcing Congress to establish precedents mandating such levels in the law?

Answer: As I stated the Social Security backlogs are down, processing times have improved and the workloads have come in below budget. It is preferable that staffing levels be based on workloads and the ability to process them, rather than to conduct administrative business under a mandatory staffing level set by law.

Abolishing the Community Services Block Grant

Question. Once again, your budget proposes to abolish the Community Services Block Grant, and consolidate its activities under the Social Services Block Grant—a net cut of $368 million in anti-poverty services. Why do you persist in submitting this request, when the response of Congress has been to maintain and expand funding for the nationwide network of Community Action Agencies?

Answer. The Administration has recommended the elimination of the Community Services Block Grant (CSBG) for three years. We request elimination of the CSBG again this year because we still believe the CSBG duplicates other Federal funding authorities, including the Social Services Block Grant (SSBG). Furthermore, we do not believe CSBG funding is vital to maintain the network of Community Action Agencies.

In FY 1986, we are requesting the full authorization of $2.7 billion for the SSBG. We realize that the funding level for the SSBG in FY 1986 is not sufficient to fund all of the activities which were funded separately in FY 1985 under the CSBG and SSBG. Nor was it our intention to do so. Rather, we chose not to request separate funding for the CSBG for the following reasons.

Most CSBG funds are used to provide administrative support for some Community Action Agencies (CAAs). CSBG funds represent only 12% of CAAs' budgets, while the remaining 86% of Federal funds available to CAAs derives from other Federal authorities, including the Low Income Home Energy Assistance Program; the Head Start program; the Social Services Block Grant; the Alcohol, Drug Abuse and Mental Health Block Grant; the Department of Energy Weatherization program; the Community Development Block Grant; the Job Training Partnership Act Block Grant; the Foster Grandparents program; the Senior Companion

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program; and the Nutrition and Supportive Services programs for the elderly. These programs all include allowances for administrative overhead which collectively, and without the increment of CSRG funds should suffice to: 1) cover the cost of administering those programs, and 2) maintain in existence those CAAs which have been performing effectively.

To the extent that CAAs deliver other kinds of services, these could be funded under the Social Services Block Grant (SSBG). The SSBG provides services to "achieve or maintain economic self-support to prevent, reduce or eliminate dependency," which mirrors the CSRG's goal of "providing a range of services and activities having a...major impact on causes of poverty." HHS has also submitted a proposal to amend the SSBG Act to add the phrase "alleviate poverty" to the purposes section to insure that funds continue to be targeted towards economic self-sufficiency when the CSRG is repealed. Currently, activities such as emergency services, day care, and information and referral are frequently being funded under both block grants.

States will have the option of continuing to fund CSRG activities which have demonstrated effectiveness. Those CSRG services which are not funded will be, we believe, ones which States feel have lower priority or have not proven their effectiveness. In these times of fiscal constraint, States can be expected to drop low priority SSBG activities in order to fund former CSRG activities which they believe have greater utility. In effect, we are giving States greater latitude to structure a continuum of services according to the particular needs of their own residents. Currently, most States have little flexibility to allocate funds in line with their unique needs since under the CSRG, they must pass 90 percent of CSRG funds through to eligible entities, most of which are community action agencies.

Question. Didn't the Congress extend the Community Services Block Grant legislation just last Fall, raising the authorization to $415 million?

Answer. The Human Services Reauthorization Act of 1984 (P.L. 98-558), enacted October 30, 1984, increased authorizations for the Community Services Block Grant (CSRG) to $400 million for FY 1985 and $415 million for FY 1986. The legislation was not extended.

CDC - ADEQUACY OF DTP VACCINE SUPPLY

Question. The Department's FY 1986 request for immunization grants is frozen at the FY 1985 level. In light of the enormous increase in the costs of DTP vaccine (from 11 cents a dose in 1982 to $2.80 a dose today), the fact that there is only one company in the United States currently willing to distribute the vaccine, the spot shortages of the vaccine that have already occured, and the absence of DTP vaccine in the CDC stockpile, are you confident that the appropriation request is adequate?

Answer. First of all, the current situation of spot shortages of diptheria-tetanus-pertussis (DTP) vaccines in the country is not

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due to lack of funds for vaccines purchases. The DTP shortages is due to two of the three producers not distributing vaccine, and production problems of the one manufacturer who was producing and distributing DTP vaccine. The 1986 budget request continues the $8 million in the CDC Immunization grants added by Congress in 1985 for the first time to help partially defray the cost to the States of purchasing DPT vaccines whose price has increased significantly in the last three years. In addition, once current spot shortages of DPT vaccines are eased and a predictable supply stream is reestablished, we will begin purchasing DTP vaccines for the vaccine stockpile inventory. For 1986, $4 million are requested in the President's budget to continue developing the stockpile. We also recognize that liability concerns are a major problem in assuring vaccine supplies. This issue is currently being debated by the Congress, the public, and the Administration. I have just recently convened meetings of the Cabinet Council on Human Resources Working Group to discuss the issues of vaccine supply and liability.

Questions Submitted by Senator Ted Stevens

Question. In the report produced last fall by the Attorney General's Task Force on Family Violence, the following recommendation was made:

> The Federal government should provide financial incentives and encouragement to the State to train criminal justice personnel, to conduct a family violence prevention and awareness campaign, and to maintain temporary resident facilities for victims of family violence. (p.96)

The Family Violence Prevention and Services Act authorized last fall as Title III of P.L. 98-457 would provide assistance to States for the activities named by the Attorney General's Task Force. If there are any reasons aside from budgetary considerations which influenced the Department's decision not to request funding for the program, please provide the Committee with an explanation of these factors.

Answer. The Administration's FY 1986 Budget does not request funds authorized in the Act because, in addition to budget constraints, we believe a new Federal program to address family violence is duplicative of existing Federal activities.

There are numerous Federal supports addressing different aspects of family violence. These programs can assist local governments in their efforts to combat the crime of family violence. Within the Department of Health and Human Services alone, there are a number of programs. For example, the Social Services Block Grant provides funds to States which may be used for a wide range of social services, including those that may address family violence (45 States use SSBG funds for protective and emergency services for adults and 47 States for such services to children). The Department also funds a number of research projects examining the issue of family violence.

The creation of an additional narrowly defined categorical program as authorized in P.L. 98-457 provides for an inappropriate

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Federal role in issues which are best addressed by local communities. Such a categorical grant program is also consistent with the Administration's objectives of allowing States and local communities maximum flexibility in addressing local problems. The most effective responses to the problems of family violence are those developed by local communities.

Question. Please advise the Committee of any action that has been taken by the Department to date to implement the family violence program, in particular in effecting the administrative provisions to provide for a government-wide coordination of family violence prevention and services activities, including research and training efforts.

Answer. The Department has undertaken efforts to implement administrative and information provisions of the Family Violence Prevention and Services Act.

Recently, the Secretary invited other Federal agencies to participate in an interagency meeting that will be held in late April that will be the initial step to coordinate Federal activities concerning the prevention and treatment of family violence. In addition, plans are underway to expand the family violence collection in PROJECT SHARE, a Department-operated human services clearinghouse. PROJECT SHARE provides assistance to local persons and groups who need information and "how-to" guidance for a wide range of issues. In an effort to assist local communities and service organizations, PROJECT SHARE is developing a family violence resource guide, which should be available within the next few months. There is also a clearinghouse the Department operates specifically for child abuse matters.

Question. In his 1984 State of the Union address, the President states:

> This year, we will intensify our drive against...horrible crimes like sexual abuse and family violence.

In the absence of any funding for the Family Violence Prevention and Services Act, please advise the Committee of how the Department intends to intensify the drive against this horrible crime.

Answer. The Department of Health and Human Services administers a number of programs which assist in combating child abuse, child sexual abuse and family violence. Some of these programs address different aspects of the problem. For example, the Social Services Block Grant provides funds to States which may be used for a wide range of social services, to prevent and treat the problems of abuse. (45 States use SSBG funds for protective and emergency services for adults and 47 States for such services for children.) The Child Abuse and Neglect Prevention and Treatment program also assists States, local governments and voluntary organizations to prevent and treat child abuse and neglect. The National Clearinghouse on Child Abuse and Neglect also serves as a national resource for service providers and researchers. Lastly, the Department administers health block and research projects related to family violence and sexual abuse.

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The Department has also undertaken activities directed at the problems of sexual abuse and family violence. The family violence collection of PROJECT SHARE, the Department-operated human services clearinghouse, is being expanded. PROJECT SHARE is also preparing a family violence resource guide, which will soon be available to local governments and service organizations.

To educate parents, professionals, and the public about the problem, the Department has prepared and disseminated publications, including, "Child Sexual Abuse Prevention: Tips for Parents"; "Recruitment and Selection of Staff: A Guide for Managers of Preschool and Child Care Programs"; and "The Educator's Role in Preventing Child Abuse and Neglect." The Department is also publishing regulations which will strengthen guidance already given to Head Start grantees to ensure that children in the program are protected from child abuse and child sexual abuse. In addition, the Inspector General will soon release a report on preventing sexual abuse in day care programs. An additional $25 million in Social Services Block Grant funds has been made available to States to train child care providers in preventing child abuse, $12.5 million will be distributed to the States for child abuse and neglect programs, and $13.5 million for research and demonstration projects addressing child abuse will be awarded this year.

Questions Submitted by Senator Mark Andrews

MEDICARE AND MEDICAID PROPOSALS

Question. In the first paragraph of your testimony, you mention the concern of the President to reduce the Federal deficit, "but yet maintain essential benefits for the nation's most vulnerable individuals and families - the poor, the elderly, and the disabled." However, two programs which are of special importance to the elderly and the poor are Medicare and Medicaid. However, the President has proposed massive cuts in these two areas - How do you justify the President's concern with his proposed cuts?

Answer. The Medicare and Medicaid proposals in the FY 1986 budet reflect our efforts to stem the rate of growth in Federal expenditures while continuing to carry out the mission of these programs and protect the most vulnerable population in this nation. Our proposals, by and large, are directed at limiting provider reimbursement and providing States with incentives to fashion their programs in the most cost-effective manner possible. Of the $5.3 billion in Medicare and Medicaid savings, $4.9 billion or 92% would be from providers, States, and the private sector.

In Medicare, we are proposing to maintain reimbursement for hospitals, physicians, and other providers at the FY 1985 level. We believe that providers will be able to accommodate this one-year freeze while still providing quality care to Medicare beneficiaries. Moreover, we will, as always, be monitoring the quality of care through such entities as the Peer Review Organizations. While some of our proposals will directly

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impact beneficiaries, we believe these reforms are programmatically sound. For example, raising the Part B premium, which will cost beneficiaries an additional $8.40 in 1986, will result in a better balance between premium financing and general revenues.

In Medicaid, we expect States to take advantage of the flexibility they have in designing their programs more efficiently, to become more aggressive in the area of quality control and to ensure that Medicaid is the payor of last resort, as a means of adapting to a limit on Federal expenditures.

In short, these proposals will go a long way towards reducing the Federal deficit without sacrificing the needs of the poor, the elderly, and the disabled.

WAGE INDEX

Question. Could you shed some light as to when the revised wage index will be announced - we understand the department is still collecting the data - is it possible to give us a date as to when we can expect the new wage index which will have an effect on Medicare reimbursement?

Answer. As you know, it has taken a considerable amount of time to secure the data necessary to develop the revised index from the hospitals. In addition, we felt it was necessary to audit the data once it was received in order to ensure its accuracy. We had anticipated that the report would be available to the Congress by March 14. A draft report has been sent to the Executive Office of Management and Budget and as soon as we have the opportunity to consult with them, the report will be transmitted to the Congress. We are making every effort to expedite this process and we expect to transmit the report shortly.

MEDICARE REIMBURSEMENT

Question. On January 24, 1985, I wrote to you expressing my concern that you had not provided for the adjustments or exceptions to the Medicare prospective payment rates of hospitals serving a disproportionate number of low income and Medicare patients, as authorized in PL 98-21, the Social Security Amendments of 1983. I have not yet received a response to my letter, and I am concerned that hospitals in Pennsylvania are suffering unnecessary financial hardship. Have you defined and identified the hospitals that are eligible for adjustments or exceptions to the prospective payment rates? I would like a list of eligible hospitals in Pennsylvania.

Answer. The Social Security Amendments of 1983 provide for exceptions or adjustments to the PPS rates as is deemed appropriate for hospitals serving a significantly disproportionate number of low income or Medicare patients. HCFA has conducted a number of studies to determine if these hospitals (mainly public hospitals) do, in fact, incur higher operating costs as a result of the types of patients served by

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these facilities. These studies have found that costs are not higher in hospitals serving disproportionate numbers of low income or Medicare patients (in some cases costs were even found to be lower). Therefore, we have determined that there is no justification for providing an exception or adjustment to the PPS rates.

As you know, the Deficit Reduction Act of 1984 requires that a definition be developed of a hospital serving disproportionate numbers of low income or Medicare patients and that a list of hospitals meeting that definition be developed and provided to the Congress. HCFA is currently developing this definition and the list of hospitals. We would be happy to provide you with a copy of the list as soon as it is available.

Questions Submitted by Senator Arlen Specter

CONSOLIDATION OF FIELD OFFICES

Question: The Social Security Administration is considering an alternative service delivery proposal which calls for the consolidation of Social Security field offices with 25 staff or less. Which field offices in Pennsylvania would be closed under this proposal?

Answer: The service delivery plan does not call for the closing or consolidation of offices with 25 or fewer staff members. No offices in Pennsylvania or any other State have been identified for closing or consolidation.

Question: How would you ensure that senior citizens living in the affected areas would not lose access to services?

Answer: The service delivery plan does provide for a systematic review by regional personnel of all offices within the region. The purpose of the plan is to ensure that SSA will continue to provide service that is tailored to the needs of the public, including new and innovative approaches to service delivery. The plan does place smaller offices in the highest priority for the initial review phase since these offices may be the most likely areas for improvement in our service delivery procedures.

COST CONTAINMENT INITIATIVES UNDER THE MEDICAID CAP

Question. The proposed cap on Medicaid payments to the states does not take into account state initiatives to contain Medicaid costs. In Pennsylvania, for example, a prospective payment system has been established for the Medicaid program, and other cost reduction measures have been put into effect. Yet, in spite of these initiatives, the Commonwealth finds

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itself the subject of reduction in the Federal payment. What incentives are you proposing to offer states which initiate cost containment measures in the Medicaid program?

Answer. Under proposed law for Medicaid, each State's share in 1986 would be held constant at the same proportion of each State's share in 1984. The 1984 proportions were chosen because 1984 is the most recent year for which actual expenditure data is available. In addition, a State which experiences excessive cost increases in 1986 will be eligible to apply for a portion of the $300 million "hardship" funding pool if that State meets criteria related to efforts to control costs.

States which have initiated cost containment measures in the past should find it easier to meet the funding limitations under the Medicaid program in 1986. For other States, this proposal should provide an incentive for the adoption of cost containment measures and improved efficiency. All States, however, should be able to become even more aggressive in areas such as third party liability collection efforts, quality control error rate reductions, and increased program flexibility through freedom-of-choice and home and community-based waivers.

Questions Submitted by Senator Pete V. Domenici

IMPACT OF MEDICAID REDUCTIONS

Question. The Administration has proposed capping the growth of Federal Medicaid payments in FY 1986 and holding growth to the medical care price deflator in FY 1987-88. In light of other cuts in State programs, do you feel that the States could absorb the Medicaid reductions without deep reductions in benefits and severely reducing the number of beneficiaries?

Answer. The Medicaid proposal should provide States with an incentive to adopt cost containment measures and improve efficiency and should not have a direct impact on either benefits or the number of beneficiaries. States should be able to live within the Medicaid limit if they become more aggressive in a variety of areas. For example, GAO reports that Medicaid pays for more than $500 million annually in uncollected third party payments, and HCFA estimates that eligibility errors result in erroneous Federal expenditures of approximately $400 million. In addition, States have been given increased flexibility in managing their programs in recent years (i.e., home and community-based waivers, freedom-of-choice waivers, flexibility to implement alternative hospital payment systems). Continued use of these measures should assist States in achieving savings.

Several additional proposals in the 1986 budget should also help States to stem increasing costs. A 1986 regulatory proposal would require child support agencies to seek medical coverage by an absent parent resulting in estimated savings of

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approximately $112 million. An AFDC proposal to institute a job search and work experience requirement would also produce significant savings.

RATIONALE FOR MEDICAID REDUCTION

Question. At a time when many hospitals are facing financial uncertainty, and the problem of health care for the medically indigent and homeless is growing, do you still feel that a Medicaid reduction of this magnitude is wise?

Answer. Actions must be taken to stem increases in Federal health care programs. Under a limited program, States will be able to target services to the truly needy, organize cost-effective systems of care and explore innovative ways of financing and delivering services. States should be able to live within the Medicaid limit by adopting cost-containment measures, reducing fraud and abuse, increasing third-party liability collections, and exploring further the flexibility which has been given to them in recent years (i.e., home and community-based waivers, freedom-of-choice waivers).

MEDICAID MATCHING RATES UNDER PROPOSED LAW

Question. This year's budget states that "within the overall spending limit, a State will receive in 1986 the same proportional share of funds as it expended in 1984. Federal payments to States would continue to match State expenditures but only up to each State's individual growth limit." Does that mean that the State match rate will be frozen at the FY 1984 level?

Answer. Under proposed law, each State's share in 1986 would be held constant at the same proportion of each State's share in 1984. The 1984 proportions were selected because 1984 is the most recent year for which actual expenditure data is available. The 1986 matching rate, however, will still be used to match State expenditures in 1986, but a State will only receive Federal matching funds up to its allotment.

We realize that after 1986, there may be a need to reapportion funds based on changing State circumstances, and we will be examining criteria (inclusive of changes in matching rates) which might be used in making reapportionments. In the meantime, we will use the 1984 base for allocating 1986 expenditures.

ARIZONA UNDER THE MEDICAID PROPOSAL

Question. How do you address Arizona, a state with no Medicaid program? Are they forever prohibited from participating in Medicaid?

Answer. In the State of Arizona, Medicaid services are currently funded under the Section 1115 demonstration waiver authority. If Arizona decides to participate in the Medicaid program in the future, a decision will be made about the

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equitable treatment of Medicaid funding for Arizona relative to the other States. Under no circumstances will Arizona be prohibited from participating in the program.

INCREASING MATCHING RATES IN FUTURE YEARS

Question. How will you assist those states with special circumstances that cause their Federal match rate to rise beyond the growth limit allowed by the medical care price deflator, e.g. states with large rural populations or a number of displaced industries?

Answer. The proposed cap on Medical Assistance Payments will distribute funds to States in 1986 on the basis of each State's relative share of payments received in FY 1984. After 1986, there may be a need to reapportion funds based on changing State circumstances (e.g. a high number of displaced industries, caseload changes) which might cause growth rates to differ from the medical care deflator. Therefore, we will be studying criteria which might be used in making reapportionments to States in future years.

HEALTH PROFESSIONS

Question. In recent years, funding for health professions education has been targeted toward programs that address the geographic and specialty redistribution of health personnel. The program has also emphasized support for minority health professions schools and disadvantaged students. For FY 1986, the Administration proposes termination of the health professions education program.

If you are completely eliminating health professions education funding, how can we continue to assure adequate access to medical education for minority and disadvantaged students?

Answer. The original intent of Federal support of efforts to increase the numbers of underrepresented minorities in health careers was to stimulate the development of recruitment and retention activities in health career training programs around the country. Generally, we have provided the seed money that enabled institutions/organizations to establish the activities for recruitment and retention of minorities in health career training. In addition, DHHS initiatives to improve debt management by increasing collections and instituting safeguards to reduce overpayments and delinquent receivables are expected to result in increases in revolving loan fund balances. We estimate that approximately $67,000,000 will be available to health professions and nursing students in FY 1986.

Question. Many rural States such as mine depend on the National Health Service Corps (NHSC) and similar programs in health manpower shortage areas. If programs such as NHSC are cut, how will these areas maintain adequate health care services?

Answer. The combined field strengths of the NHSC Federal, PPO, and PPA reflect a total of 3,507 assignees that will be serving

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in HMSAs by the close of FY 1986, an increase of 405 assignees over FY 1985. Although funding for the NHSC Scholarship program has been discontinued in the FY 1986 President's Budget, the supply of NHSC obligors in the pipeline for subsequent NHSC placement through 1990 will provide for the short term personnel requirements of the NHSC continuing health care services to underserved rural and urban populations.

Consideration of various options to provide personnel for health manpower shortage areas in lieu of NHSC Scholarships are currently under review at the Department. These recommendations would culminate in the legislation proposals to ensure a continued supply of NHSC assignees in the 1990's.

INDIRECT COSTS - RESEARCH GRANTS

Question. From 1972-1982, indirect costs increased from 20.6 percent to 30 percent of total NIH grant costs. In large institutions almost one-third of this overhead is for departmental administrative expenses, such as department head's and dean's salaries. Both your department and GAO have studied indirect cost problems and recommended changes in the allocation methods. Currently, the issue is being studied by the Office of Science and Technology Policy. Since the recipient institutions reap substantial tangible and intangible benefits from these grants why should we pay indirect costs at all? Would you support efforts to scale back indirect costs and, at the same time use savings to increase the number of grant awards? Will you propose changes in indirect cost regulations this year? If so, please describe the anticipated proposals as well as the timetable associated with any changes.

Response. Indirect costs are those expenses incurred in carrying out a federal research project that cannot be readily traced to a specific project. It has been the policy of the government to bear its fair share of these costs for both profit and nonprofit institutions. No, I do not support the concept of using indirect cost savings to fund additional grants. Although we have proposed to "freeze" indirect cost rates at the 1985 level, the intent is not to increase the number of grant awards; but rather, to control the rapid rise in indirect costs. The study by the Office of Science and Technology Policy is expected to be finished by mid-year. We expect that report to include options and recommendations for changes in OMB Circular A-21, which establishes principles for educational institutions for determining allowable costs for reimbursement.

RESEARCH PROJECT GRANTS - NUMBER

Question. In FY 1984, HHS awarded 5,493 new and competing NIH grants. For FY 1985, Congress appropriated additional funds to raise the level of new and competing research grants to 6,500. NIH made their first round of awards on the basis of the 6,500 level. However, since that time, the Administration has decided to support only 5,000 new and competing grants in FY 1985 and to begin to fund some of these awards for a multi-year period. Why are you funding only 5,000 new and competing

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grants instead of the 6,500 intended by Congress? Since you reduced the number of awards from 6,500 to 5,000 after some FY 1985 grants were awarded, will the funding level of the remaining awards have to be adjusted downward? Please explain how the multi-year funding policy affects continuation grant award levels. Specifically, will the three-year grants funded from FY 1985 receive the same amount of money as they would have received if they were funded as a one-year grant in FY 1985 and as continuation grants in FY 1986 and 1987? In your FY 1985 budget, presented almost four months after the close of fiscal 1984, you projected NIH grants at 5,200. This year the actual number of grants for FY 1984 is shown as 5,493. How could your estimate be off by so many grants?

Response. Our prime concern in structuring the 1986 President's budget was to minimize the need for spending increases between 1985 and 1986. The additional 1,500 grants at the 6,500 level would generate approximately $307 million in continuation costs above the 1986 budget request. Such an increase would have made it impossible to maintain the "freeze" policy and still award anywhere near 5,000 new and competing grants in 1986 without making unacceptable offsetting reductions in other research mechanisms.

A number of projects were identified for award as a result of council review in October 1984. Institute paylines for these grants are generally 10-15 points higher than that which would be possible at the 5,000 level. Some of these grants have been paid, and a number have been held in reserve pending completion of the remaining review cycles. We do not expect the paylines resulting from the various reviews to differ substantially. Multi-year awards will receive the same amount of funding for the period as they would if each year were separately funded.

The 1984 actual number of new grants differed by 493 from the 5,000 estimate for the following reasons:

289	Average grant award (actual) less than estimate used for budget formulation.
36	Reclassification of projects from other mehanisms.
43	Updated estimate of small business set-aside.
50	Release of funds reserved for pay raise.
8	AIDS supplemental.
67	Congressional add-on.
493	

AFDC ERROR RATE WAIVERS

Question: When does the Department plan to announce the waiver amounts for the pending AFDC sanctions?

Answer: The Associate Commissioner of the Office of Family Assistance and the Commissioner of Social Security have completed their review of the waiver requests and have forwarded their findings to the

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Office of the Secretary. We are now considering the SSA findings and will make the final decision on the waivers soon.

This first waiver process has been a lengthy one. Feedback from the first year process will simplify the review for future years.

Question: What States are involved, and what amount is waived for each State?

Answer: The States facing potential disallowances for FY 1981 are:

Alabama	New Jersey
Arizona	New Mexico
California	New York
Colorado	Ohio
Connecticut	Oklahoma
Florida	Puerto Rico
Hawaii	South Carolina
Idaho	South Dakota
Indiana	Tennessee
Kansas	Texas
Maine	Utah
Maryland	Vermont
Minnesota	Washington
Nebraska	Wyoming

The potential waiver amount for each State, if any, has not yet been determined by the Secretary.

CLOSURE OF DISTRICT OFFICES

Question: Do you have plans to downgrade or close certain Social Security district offices? What are your criteria for considering an office for downgrading or closing?

Answer: The budget does not include any specific plans to downgrade or close existing offices. SSA has had Administrative Directives System (ADS) Guide procedures in place for many years to address the issue of field office location and classification. The Guide uses criteria such as population numbers and characteristics, numbers of beneficiaries and recipients in an area, accessibility of facilities, etc., to upgrade as well as downgrade or close facilities where warranted.

We are currently updating these procedures by putting into place a disciplined process that calls for an ongoing, long-range review of all of our field facilities so that we can determine whether the organizational structure that has been in place for decades makes sense in today's environment.

If the status quo best serves the people, we will retain it. But where population shifts, demographic

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changes, and technological improvements warrant change, we will make changes.

Our review will take several years, and our overall goal remains unchanged - to provide accessible and responsive service to the American public in the most cost-effective manner possible.

The Agency is currently developing a uniform SSA-wide service delivery plan which will more clearly define the above mentioned criteria. The primary thrust of this methodology is not to reduce the number of offices, or justify the status quo; but to allow the regions to determine the best service delivery approaches to provide accessibility and responsive service to the American public in the most cost-effective manner possible.

Question: Will you provide us with a State-by-State list of these offices?

Answer: Since there is no plan to downgrade or close existing offices, a State-by-State listing of such offices does not exist.

Questions Submitted by Senator William Proxmire

INDIRECT COSTS

Question. Indirect costs are currently consuming about one-third of each biomedical research dollar. Last year in a response for the record you indicated that the Office of Science and Technology Policy (OSTP) was expected to make recommendations regarding indirect cost policy before the end of calendar year 1984. Can you give us a status report on those recommendations?

Response. In February 1984, the Secretary asked OSTP to undertake a government-wide review of indirect cost policies. Among the concepts under consideration in the study is a fixed percentage allowance for the various categories of administrative costs in university indirect cost rates. The Department is providing data and technical assistance in this effort. We have been advised by OSTP staff that a report is expected by mid-1985.

CARDIAC PACEMAKERS

Question. Secretary Heckler, as you know, we have corresponded regarding the recent news reports that the Medicare trust fund has been footing the bill for implantable cardiac pacemakers which have proven defective and the trust fund must then foot the bill for the replacement operation. At an average cost of $10,000 per operation, you indicated to me that Medicare

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might pay out a minimum of $27 million for devices which proved defective and were replaced.

My concern is how we begin to approach the most basic question: who foots the bill for replacement of defective devices? How do we best protect the trust fund? With our technological capabilities growing by leaps and bounds, the prospects of many implantable devices, each with a hefty price for implantation and replacement if they prove defective, means that we need to develop a consistent policy on how to approach the question of manufacturer liability.

The Medical Devices Act of 1976 gives your Department the authority to seek recovery from manufacturers if certain criteria are met and your Department is now considering a case involving the Minneapolis firm, Medtronics.

First, can you outline for the committee your Department's approach to the entire question of manufacturer liability in cases such as the cardiac pacemaker poses?

Second, when can we expect a decision from the Department on the Medtronic case?

Answer. Section 518(b) of the Federal Food and Drug and Cosmetic Act provides the Department with the authority to require manufacturers to assume the cost of replacement operations if the following four criteria are met:

— The device presents an unreasonable risk of substantial harm to the public health;

— There are reasonable grounds to believe that the device was not properly designed and manufactured with reference to the state-of-the-art at the time it was designed and manufactured;

— There are reasonable grounds to believe that the unreasonable risk was not caused by someone other than the manufacturer, importer, or distributor (e.g., the user); and

— Notification of users alone is not suffcient to eliminate the unreasonable risk; and repair, replacement, or refund is necessary to eliminate the risk.

In addition, under section 1862(b) of the Social Security Act, the Medicare program may initiate legal action against responsible parties and liability insurers to recover Medicare payments if no liability claim is filed by the beneficiary or may recover from any liability insurance payment made to the beneficiary. We believe this provision is applicable in cases involving defective devices if the patient has a claim against the product's manufacturer based on the defect, and the claim is covered by the manufacturer's liability insurance. Success in effecting recovery under this provision is, of course, dependent on establishing the manufacturer's liability, which may be complicated by varying State laws on liability. To the extent

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that manufacturers comply with the terms of their warranties for replacement of devices, Medicare-covered expenses are not incurred. However, where a manufacturer agrees to pay only a fixed amount for uninsured medical and hospital expenses incurred to replace such a device, the Medicare program has no recourse under current law except to make a conditional payment and pursue recovery under the liability insurance provisions. Accordingly, we have instructed our contractors to make conditional payments in the cases involving defective pacemaker leads. At the same time, we are pursuing recovery from the manufacturer or its liability insuror.

With respect to the Medtronic case, the Food and Drug Administration (FDA) is evaluating the situation to determine if the section 518(b) criteria, described above, are met. One of the most difficult issues in ths case, is in determining whether the pacer lead involved was designed and manufactured according to the state-of-the-art in 1979, when it was first produced. We expect a final FDA decision very soon.

Questions Submitted by Senator Lawton Chiles

INFANT MORTALITY

Question. The United States ranks 12th among developed nations in infant mortality. Technology has gone about as far as it can in saving high risk, low birth weight infants. On the other hand, we are still making astounding progress in life extension --the fastest growing segment of the population is the over-85 age group.

I am troubled that we are not doing as well in reducing the death rate of infants. We know that a critical factor in infant deaths is low birth weight. We know that alcohol consumption, drug abuse, and cigarette smoking all contribute to the risk. We know what could be accomplished with better prenatal care and nutrition. We do not have an answer to sudden infant death syndrome.

What is your agency doing to combat infant mortality? Do you have the problem as a top priority and is there a concerted effort underway?

Answer. Infant mortality and low weight birth are top priority problems in the Public Health Service. They are the subject of major objectives for the nation for 1990. The Assistant Secretary for Health has been in touch with all State health officers to warn them of the seriousness of these problems and work out coordinated approaches relative to research, statistical analyses, epidemiologic approaches, etc. The Assistant Secretary for Health wrote a lengthy article on infant mortality and low weight birth which was published in Public Health Reports and has been widely disseminated.

The PHS is helping to support the wide dissemination of the recent Institute of Medicine Report so that States and communities are currently informed of the nature and scope of the problem and encouraged to act upon them in the allocation of their block and other resources.

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We are making available the services of expert teams to help States and communities in the assessment of infant mortality issues and problems.

We have given priority to improvement of State perinatal care systems in our MCH special project grant efforts -- supported with funds set aside from the MCH Block Grant.

The PHS has undertaken a special initiative to increase availability of effective perinatal care in the 649 community and migrant health centers which reach many of the Nation's underserved populations.

A variety of research activities are underway or being encouraged which hopefully will be helpful in reducing rates of low weight births and infant mortality.

In our 1986 budget justification, we have proposed to reduce Washington-administered project grant activities and increase -- by about $12 million -- block grant allocations for State service efforts.

Question. Is there any kind of coordination within your agency to tackle the problem in a comprehensive way -- with research, through health education and services, teen counseling, and the effort to reduce alcohol, drug abuse, and smoking?

Answer. Yes, there is extensive coordination. I would like to submit for the record a recent report from the Division of Maternal and Child Health which summarizes our efforts in this area.

Question. Since nutrition, housing, and even environmental factors can play a role in this, is there any kind of interagency effort underway between your department and other Federal agencies?

Answer. The MCH program participates in an interagency committee on nutrition, though not one especially constituted in response to the problem of infant mortality. No Federal interagency committee has been formed to deal with the problem. In our view, however, except for demonstration or training projects, the interagency action which is vital is that at the State or local levels. Planning for actual service development and delivery efforts must take into account the various interrelationships among State and community health and health related organizations whose efforts require linkage and active coordination in multiple aspects. These are among the reasons that we are so supportive of the block grant approach and the placement of authority and resources in close proximity to the problem. We see the cooperation and coordination occurring at the service delivery level as those which will be most productive relative to infant mortality reduction.

Question. You know that the south has the highest rate of infant mortality. Are the funds and the efforts in our different programs and initiatives that relate to infant mortality adequately directed to this area of the country?

Answer. As part of their Effective Pregnancy and Infant Care Initiative to reduce infant mortality in the United States, the Division of Maternal and Child Health has awarded a grant to the

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Southern Governor's Association to help support a newly created Southern Regional Task Force on infant mortality. The Task Force will be comprised of high level policy makers, substantive experts from the health and academic communities, and representatives from key health and government related organizations. There is a short-, medium-, and long-term intended impact for the project. The short-term impact is to increase awareness of key health policy makers of the problems of infant mortality and low birth weight as well as the varied policy and programmatic solutions. The medium-term intended impact is to assist State policy makers to improve their approaches to address the problems of infant mortality and low birth weight by transferring ideas and experiences among States and across professional groups. The long-term intended impact of the project is to reduce the incidence of infant mortality and low birth weight in the South.

Special Projects of Regional and National Significance (SPRANS) support a variety of perinatal and infant care activities relevant to infant mortality/low birth weight and we expect a very substantial share of this year's applications will originate in southern States.

Question. The Institute of Medicine has suggested a preventive approach to Infant Mortality. This study claims that prenatal and nutritional care to the high risk mother would cost less than all the high tech and intensive neonatal care required by low birth weight infants.

How do you justify the cuts proposed for health care and services for this very high risk population — women between 15 and 39 on welfare with less than 12 years of education?

Answer. The 1986 budget proposal for the Medicaid program would limit Federal Medicaid payments in FY 1986 and hold growth to the medical care price index in future years. This proposal should provide States with an incentive to adopt cost containment measures, reduce fraud and abuse, increase third-party liability collections, and improve efficiency, and we do not expect it to have a direct impact on benefits. In fact, in 1985, the Deficit Reduction Act expanded Medicaid coverage by requiring States to provide categorically needy coverage to certain categories of pregnant women and children who meet AFDC income and resource requirements. Included in this mandatory coverage requirement are first-time pregnant women and pregnant women in two-parent families where the principal breadwinner is unemployed. These new coverage requirements will result in an additional $105 million in Federal Medicaid costs in 1986 and $700 million between 1985 and 1989.

Question. Have you costed out these cuts in terms of increased infant mortality, or even high cost neonatal intensive care?

Answer. Reductions in Federal payments in the Medicaid program should not have a negative effect on progress made in reducing the infant mortality rate. Infant mortality rates continue to show a decline from year to year, and have in fact been cut almost in half since 1970. Because of requirements in the Deficit Reduction Act, many States are now expanding

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eligibility to pregnant women and young children, and we hope that these additional services will have a positive impact on infant mortality. States are now required to cover first-time pregnant women, pregnant women in two-parent families where the principal breadwinner is unemployed, and children born after October 1, 1983, up to age 5, in two-parent families (provided that these individuals meet AFDC income and resource requirements).

Question. The almost 50 percent reduction in infant mortality is almost wholly due to technological advances in treating low birth weight infants. There has been virtually no reduction in the incidence of low birth weight.

What do you propose we do to prevent low birth weight?

Answer. Recognizing the proliferation of the activities directed toward Low Birth Weight (LBW) prevention and Infant Mortality (IM) reduction supported by the Public Health Service (PHS) and by State and local governments and private organizations, the PHS established the LBW Prevention Work Group in March of 1984. The work group, which reports to the Assistant Secretary for Health, is comprised of representatives of key PHS organizational components which have maternal and child health (MCH) responsibilities, i.e., Division of Maternal and CHild Health (DMCH), National Institute for Child Health and Human Development (NICHD), National Center for Health Statistics and the Centers for Disease Control. The mission of the group is to formulate and articulate a cohesive PHS strategy including policy and program options for reducing the number of LBW and the rate of IM in the U.S. The group is chaired by the Direct of DMCH and the Co-Chairman is the Director of the NICHD. the work group has coordinated with and contributed to the work of the IM Subcommittee of the Secretary's Black and Minority Health Task Force. This work group has assembled MCH experts from the PHS and has served as an immediate source of expert scientific and policy advice for the Assistant Secretary for Health on matters relating to IM and LBW rate. A current prime focus of attention is the development of the review protocols to be employed by expert IM review teams which will be available to requesting States.

Statement of Senator Quentin N. Burdick

Health Professions Assistance

Madame Secretary, I appreciate your coming to our subcommittee today. Although most of my questions about the HHS budget will be addressed to others in your department who will be appearing later, there are a few important points I want to make and questions I would like to raise.

First of all, I want to associate myself with those on this subcommittee who have expressed dismay at your plans for 1985 NIH appropriations. Congress was very clear in its directions for NIH, and I feel, as many other do, that you are doing an "end run" around us. I have joined in cosponsoring a joint

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resolution directing that the 1985 funds be spent as directed in our 1985 Appropriations bill, and I would hope that resolution will be passed and enforced.

Second, I am deeply concerned about the impact many of the cuts you have proposed will have on rural America. I can say, here and now, that I do not support these cuts. I want to outline briefly why they will hit so hard on rural areas and ask a few specific questions about some of them.

QUESTIONS SUBMITTED BY SENATOR QUENTIN N. BURDICK

Question: You have eliminated funding for virtually all the health professions. I cannot agree with such wholesale cuts, especially in the areas of Nursing and Family Practice. While I realize there is no longer a shortage of doctors and nurses in many metropolitan areas, North Dakota and other extremely rural areas continue to experience severe health professions shortages. Family practice doctors and nurses, especially nurse practitioners, fill an essential role in our rural areas, and cuts in support for their training will hit rural America especially hard.

Answer: Our budget policy is premised on the fact that Federal government subsidies for training health professionals are no longer needed. Nearly 20 years ago the Federal government began to provide a financial stimulus to overcome gross overall national shortages of personnel. These shortages have been solved. While there may be selected areas of the country with unique shortage problems, the nation as a whole is facing surplus.

To overcome these pockets of shortages will require solutions outside the education system. Training more doctors or nurses is not the answer. States must develop appropriate service support systems to meet the health care needs of their citizens. Rural clinics, supported through the Community Health Center program, and National Health Service Corps doctors are two such systems continued in this budget. Other States are giving students scholarships during their training in order that the student will eventually relocate in an unserved rural location. These seem to be more appropriate solutions to the shortage problem described in North Dakota.

SERVICE TO THE PUBLIC

Question: I understand you have plans to eliminate thousands of field office jobs over the next 5 years--starting with the elimination of the smallest offices.

Again, this is going to have a disproportional impact on rural areas. It is my understanding that internal SSA memos state that travel time "cannot be a consideration" in looking at closure of offices in rural areas--yet it is in the rural areas where so many

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older people reside. In many of North Dakota's counties, the over-62 population makes up over 20 percent of the population, yet you will be closing the small SSA offices that serve many of these counties and asking these older people to drive hundreds of miles to another SSA office.

I'd like to know just how these older people living in rural areas are going to be protected if these manpower cuts go through.

Answer: The reduction of 17,000 full-time equivalents over the next 6 years and our planned consideration of the continued need for our smaller offices are not related. The staff reduction will be permitted by the introduction and phasing in of enhanced automated procedures resulting from our Systems Modernization Plan and by other improvements in operational procedures and management effectiveness. The reductions will be achieved through attrition and retraining of personnel. Furthermore, no personnel reductions will be effectuated until we are ensured that the automated procedures are fully in place and working properly. We are committed to a continuation of quality service to the public.

SSA has had Administrative Directives System (ADS) Guide procedures in place for many years to address the issue of field office location and classification. We are currently updating these procedures through an ongoing, long-range disciplined process that calls for a review of all of our field facilities to determine whether the organizational structure that has been in place for years make sense in today's environment.

There is no plan to close a preconceived number of offices. If the status quo best serves the people, we will retain it. But where population shifts, demographic changes, and technological improvements warrant change, we will make change.

MEDICAID MATCHING FORMULA

Question. The Medicaid matching formula is written in such a way that farm states have historically experienced unusually wide swings in their federal matching rates from biennium to biennium. Other states, where farm income does not play such a central role do not seem to experience this problem the way rural states do. North Dakota's rate, for instance, is scheduled to drop by 6 percentage points in 1986. Thus, just as we face the worst farm crisis in decades and are struggling to provide needed services, we are going to lose some $15 million.

Senator Andrews and I put language in the 1985 Appropriations bill urging that HCFA look into this. We believe there are some technical changes that could be made to make the formula more equitable for North Dakota and other farm states

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without undertaking a major formula change. We have yet to receive any indication that HCFA is following this directive, despite two letters to Carolyne Davis on the matter.

Thus, my question here is, what is the status of HCFA's study on the Medicaid formula problem affecting rural areas?

Answer. Any change in the Federal Medical Assistance Percentage (FMAP) formula will affect both the Medicaid and the Aid to Families with Dependent Children (AFDC) program, and therefore, it is necessary to coordinate activities with regard to this issue between these two programs. Preliminary discussions have been held with the Social Security Administration on the FMAP methodology, and we will be looking at this issue in the coming year. We also understand that GAO and the Department of Treasury are reviewing a number of grant formulas, including FMAP.

Question. Another issue pending in your department which is of enormous interest to rural states is the revised wage index, which was supposed to be published several months ago. Hospitals in my state are extremely anxious to put this updated and more accurate index into effect.

My question is one I am sure you have heard before, but which needs desparately to be answered--How soon can we expect the new index to be published?

Answer. As you know, it has taken a considerable amount of time to secure the data necessary to develop the reused index from the hospitals. In addition, we felt it was necessary to audit the data once it was received in order to ensure its accuracy. We had anticipated that the report would be available to the Congress by March 14. A draft report has been sent to the Executive Office of Management and Budget and as soon as we have the opportunity to consult with them, the report will be transmitted to the Congress. We are making every effort to expedite this process and we expect to transmit the report shortly.

Question: The Old Regional Family Resource Centers, funded until last October by the Office of Human Development Services, were extremely valuable to the smaller, rural states. The Region VIII center provided invaluable resources information and technical assistance to our state agencies trying to implement programs on adoption assistance, child abuse prevention, run-away youth, and other family service programs. As federal support for these programs dwindled, the resource centers become increasingly important in helping the states to share ideas and information.

Despite our efforts, the regional resource centers were not funded in fiscal year 1985. Instead, HHS promised to publish guidelines for new grants for centers designed to provide the same kinds of services to the states. The Regional Resource Centers were to be eligible to apply for these grants.

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I was one of several members of Congress who wrote you on December 18 asking when these guidelines would be published. We have yet to receive a response to this letter or, more importantly, receive word about the guidelines. I have here a copy of the letter we sent you last December, and I would appreciate a response to it, including information about the new grants, as soon as possible.

Thank you, Madame Secretary. That concludes my questioning.

Answer: Program Announcement No. CWS-RC-85-1, Resource Centers for Child Welfare Services; Availability of Funds and Request for Applications was published in the Federal Register on April 1, 1985. This was an announcement of a separate grant competition for approximately $2 million for which applications were accepted through June 17, 1985. Nine priority areas were announced and grants will be awarded in those nine areas. They are: 1) Foster Care; 2) Adoption Services; 3) Family Based Preventive services; 4) Services to Developmentally Disabled Children in Child Welfare Systems; 5) Youth Services; 6) Child Welfare Program Management and Administration; 7) Legal Resources on Child Welfare Programs; 8) Child Abuse and Neglect; and 9) Prevention and Treatment of Child Sexual Abuse.

Any State, local, public or non-profit organization or agency including accredited colleges and universitites were able to submit applications. Joint applications were encouraged. Approximately 25 percent of the total cost of projects must come from a source other than the Federal government. Other requirements for application are included in the copy of the Federal Register that follows.

Notification of grant awards will be made at the end of September, 1985.

Questions Submitted by Senator Tom Harkin

WAGE INDEX

Question. First, I would like to ask you when we are going to receive the report on the revised Urban and Rural Wage Indices which was due last August. I understand that in testimony before the House Appropriations Committee last Thursday, you stated that the report being prepared by your Department on the Area Wage Indices to be used in the Medicare Prospective Payment Program would be transmitted to Congress in two weeks. By my calculations, that would be by Thursday, March 14. Will you still be meeting this deadline? Will all of the supporting data be provided as well? If not, why not? If not, when will this report be sent to us? Why the delay?

Answer. We are making every effort to expedite transmission of the report on the hospital wage index to the Congress. We had anticipated having the report available to the Congress by March 14, after consultation with the Office of Management and Budget. A draft report was sent to the Office of

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Management and Budget on March 11 and we expect to receive their comments shortly, at which time it will be transmitted to Congress.

The report will contain all the data on the revised indices as well as our analysis of the data. We would be happy to provide you with any additional information you might require once you have received the report.

As you know the revised index will have important implications for many hospitals, particularly since the law requires that it be applied retroactively. Therefore, we felt that it was imperative that every effort be made to ensure the accuracy of the data. In order to develop the revised index, a survey was initiated on March 16, 1984, to collect the required data from the hospitals.

Unfortunately, the response to the survey was disappointing. HCFA was forced to make repeated attempts to obtain correct data from the hospitals. In fact, some hospitals were still submitting data as late as January 1985. In order to ensure the accuracy of the data once it was obtained, HCFA and the Office of the Inspector General then audited the data from a sample of hospitals. All these factors led to the unanticipated delay in the development of the report.

Question. The American Medical Association News of February 22, 1985, reports that this area wage index report will provide very favorable findings for rural hospitals in the country. According to this article, about half of the nation's rural hospitals will be getting more money per DRG while the other half will be getting about the same amount per DRG as they now receive. Moreover, these findings have been validated by an HHS audit of 64 hospitals in the survey. Can you verify these findings for us now?

Answer. The wage index report, which will be transmitted to the Congress shortly, will contain a full analysis of the impact of the revised wage index on both urban and rural hospitals. I would note, however, that our findings do not coincide with those reported by the American Medical Association News. Rather, we found that while about half of both the urban and rural hospitals would realize an increase in reimbursement, half would experience a decrease in payment per DRG. That is why we felt it was imperative to conduct additional audits and verify the accuracy of the data.

Question. I understand that you have done a second audit of the findings of your initial area wage index report, in which you examined the data from 110 hospitals whose DRGs would change by 10 percent or more. Can you tell us what the findings from this second audit were? Will changes in the data from these 110 hospitals affect the area wage indices of the rest of the hospitals in the country?

Answer. As you point out, a second audit of 110 hospitals was conducted for those hospitals whose DRG payments would change by 10 percent or more. While the changes in the data as a result of this audit would be greater than those from the original audit, which was based on a random sample of 50

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hospitals and 14 hospitals with large variations, in most cases the changes were not significant. The area wage indices of the rest of the hospitals in the country will be affected, however, the impact will not be substantial.

Question. As you well know, this area wage index report is merely the first step in correcting some of the problems in the Medicare Prospective Payment System. Following the transmittal of this report to Congress, you will be required to adjust payment amounts to hospitals retroactively to October 1, 1983. I have two questions:

How long will it take the Department of HHS to work out procedures or a formula to make the required adjustments? (i.e., when will hospitals receive additional payments or be required to make reimbursements to HHS?)

What will this formula for adjustments look like: A lump sum payment or bill due to each hospital? A phase-in reimbursement or payment schedule? Some other method.

Answer. We do not expect it to take very long to work out the procedures to make the required adjustments. However, we do believe that given the significant impact the revised index will have on some hospitals, it is important that hospitals be given an opportunity to comment and that the Congress have the opportunity to carefully review the report.

No decisions have been made at this time on whether adjustments will be made on a lump-sum basis or payment schedule. We are looking at a variety of approaches including a phased-in payment schedule.

Question. As further follow-up to this area wage index report, you are required to study and report to the Congress on proposed criteria under which future adjustments in Medicare Prospective Payments to hospitals could be made. This portion of the Deficit Reduction Act is critical to enable hospitals in the future to have some means to appeal their DRG levels. When will this report be submitted to Congress?

Answer. The Deficit Reduction Act of 1984 requires that we study a number of issues, including payments to hospitals on a regional basis and a review of the urban/rural payment differential, particularly with respect to the advisibility of varying the labor and non-labor components among DRGs. HCFA staff have determined that it will take at least a year to produce a responsive report. The series of urban-rural studies, including the ones addressed in the Deficit Reduction Act, will be carried out through a cooperative agreement with the Brandeis University Research Center. In addition, they will be studying the influence of regional economic factors on hospital costs also specified in the Conference Report.

These issues will be addressed beginning with the report on sole community hospitals and rural teaching or referral centers mandated by the Social Security Amendments of 1983 and due by

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April 1, 1985, and ending with the December 31, 1985 report on the feasibility of eliminating or phasing out the separate urban-rural rates.

Questions Submitted by Senator Dennis DeConcini

OCCUPATIONAL HEALTH

Question. 5 U.S.C. 7901 authorized Federal agencies to provide health services to promote and maintain the physical and mental fitness of Federal employees and requires the Federal agencies to consult with the Public Health Service (PHS) and consider its recommendations prior to establishing such services.

Implicit in this legislation is the requirement that the PHS have a staff to develop standards for Federal occupational health services and to provide the required consultation.

It is proposed in the President's FY 1986 Budget recommendations that the provision of these services by the PHS be funded by reimbursement from the agencies requesting consultation.

What studies have been done or what discussions have been held with the Federal agencies to assure that they will continue to seek consultation and pay for it in sufficient volume to support a staff adequate to meet the PHS responsibilities under the law to assure that the occupational health services provided are appropriate and efficient?

Answer. No studies have been done nor discussions held to date to determine whether Federal agencies will continue to seek consultation and pay for it in sufficient volume to support the staff needed to meet PHS responsibilities under 5 U.S.C. 7901. In FY 1984, the Division of Federal Employee Occupational Health (DFEOH) received $1.2 million in direct appropriation to support the cost of its standards development and consultation services. In FY 1985, $600,000 was appropriated. In both years, agency reimbursements are provided for the balance of support. A fee schedule for standards consultation and evaluation services is now being developed. A series of regional meetings are now being planned to discuss PHS's recently developed standards and criteria for a comprehensive occupational health program and the consultation services which PHS will be able to provide the agencies on a reimbursable fee basis to help them meet the standards and to contract for services. It is hoped that the agencies will recognize not simply their legal responsibilities to consult with PHS prior to providing services, but the potential benefits of such consultation.

Question. Under this proposal to discontinue Public Health Service direct operation of the 160 health units and 7 employee assistance programs by its present combination of full-time Federal employees and contract staff and national contracts for laboratory and EKG services and supplies and equipment, agencies will have the option of either operating the program with their own direct hire staff or contracting out the complete operation of the health units.

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Given everyone's interest in holding down the cost of government, what are present per capita costs and what data do you have regarding future costs under the proposal, particularly if the agencies have to contract out?

Answer. Our current average per capita cost for the 154 DFEOH direct operated health units is $65.08. Seven health units have contracts for personnel only with certain services, such as laboratory and EKG, provided by DFEOH through national volume discount contracts. These seven contracted health units cost $73.47 per capita. Contract costs are hard to estimate for this type of service given the size, geographic distribution of the health units and unique aspects of each unit's requirements. Until we receive specific requests for advice from the various agencies stipulating the kinds and level of services they wish to provide their employees under the new operating mechanism, any estimate of future per capita cost would be purely speculative.

Question. And, if the costs go up, what information do you have that the agencies in the face of tighter budgets will not be forced to reduce or stop services?

Answer. We have no precise overall information on whether agencies will continue services if costs increase. However, there has been no reduction in overall funding for these services. There is no reason to believe services will change.

Question. In October 1983, at a conference co-sponsored by your Department, General Motors, and the Metropolitan Life Insurance Company, you and your staff heartily endorsed the concept of worksite health promotion as did the many representatives of the private sector. In March 1984, President Reagan also endorsed the concept and stated:

> "Disease prevention and health promotion are in all of our interest....The illness of employees is a costly proposition. A healthier work force means higher productivity, reduced absenteeism, and less overtime. In the long-run it also means a education in the cost of employee health benefits....Because working people spend about half their waking hours at work....the employer can influence his or her employees to change some bad habits that heavily affect ones health."

Last summer, Senators Abdnor, Bingaman, and I requested that the Office of Personnel Management in consultation with your Department study the status of worksite health promotion within the Federal government. It is my understanding that such a study is now being undertaken by the Division of Federal Employee Occupational Health in cooperation with the OPM and the GSA. It is also my understanding that the Division of Federal Employee Occupational Health, through the health units is already conducting a considerable amount of health promotion activities for Federal employees.

What information can you supply us with concerning how much worksite health promotion is now being provided by the PHS operated health units?

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Is it wise to place the current national system for delivering such services to a large number of Federal offices and then providing consultation and guidance to all Federal agencies on this matter in jeopardy prior to the completion of the study and a decision on Federal policy on his matter?

Also, what studies have been done of the potential impact on quality and cost of breaking up this national system of occupational health services?

Answer. Health promotion has been an integral part of the Division of Federal Employee Occupational Health (DFEOH) program since its inception. Visits to the health units, the employee health examinations and consultation with managers are received as preventive health measures intended to maintain work productivity and reduce Federal financial liability.

In 1984, the 160 health units of DFEOH which serve 270,000 Federal workers, provided 3,926 health promotion programs. Over 150,000 participants received the benefit of these programs designed to assist them in modifying their health behavior in respect to specific health risks.

Two-hundred-seventy-five (275) occupational health nurses of the Division have been trained to conduct comprehensive health promotion programs. A special 6 month training program, including formal classroom instruction and practical on-the-job experience, provided an approach to defining worksite health problems, conducting health needs assessments of employees, setting realistic and measurable program objectives, selecting effective educational methods and evaluating the results of such programs.

The following table provides insight into the distribution of programs and participants by major health categories. This list is in decreasing order of program participation.

DFEOH Health Promotion Programs, 1984

Major Health Category	Participants	Programs
Hypertension	41,031	226
Smoking	29,487	328
Cancer	22,592	510
Glaucoma/Vision	16,279	213
Physical Fitness and Exercise	13,144	220
Diabetes	10,127	349
Nutrition	8,671	513
Hearing	5,513	108
Stress and Violence	4,970	226
Occupational Safety and Health	4,647	83
Cardiovascular	3,398	132
Mental Health	2,209	100
Alcohol Misuse	1,760	81
Cardio-Pulmonary Resuscitation	1,416	72
Drug Misuse	1,051	57
Sex Education and Family Planning	477	67
All Others	84,090	318

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The Average number of health promotion programs conducted per DFEOH health unit was 24 or 2 per month.

It is our expectation that the agencies will continue to consult with the PHS so that the scope and quality of the services will be maintained regardless of the provider. The DFEOH will continue to set standards on Federal occupational health programs to assess the scope of quality and objectiveness of services.

No specific studies have been done on the cost and quality impact of breaking up this national system. As indicated earlier, we hope the quality will be retained by careful drafting of contracts and even more careful monitoring of the contracts by the agencies.

Questions Submitted by Senator Albert A. Gore, Jr.

ORGAN TRANSPLANTATION

Question. Could you please submit for the record, the Department's plans for the Office of Organ Transplantation for FYs 1985, 1986, 1987, and 1988; including for each year the planned operating budget, the location of the office within the PHS organizational chart, and proposed staffing.

Answer. Although the National Organ Transplant Act was passed at the beginning of fiscal year 1985, funds were not appropriated to implement the Act. The Department has implemented Title I of the Act which required the establishment of a Task Force on Organ Procurement and Transplantation.

The Office of Organ Transplantation was established in the Office of the Administrator (OA), Health Resources and Services Administration (HRSA). The initial establishment of the Office in the OA, HRSA, was to assure the highest level of program direction and oversight during the early stages of implementation of the National Organ Transplant Act. We anticipate, however, that the Organ Transplant program ultimately will be transferred to one of HRSA's bureaus. The Office currently is staffed by seven professionals and three clerical, all of whom were existing Department employees. During FY 1985, the staff has been charged primarily with providing support to and liaison with the Task Force, conducting a national public information program, and gathering data on existing organ transplantation networks and registries and organ procurement organizations.

Sources of funding to provide support for the Task Force activities in FY 1985 currently are being considered within the Department. Budgets for the program have not been proposed for FYs 1986-1988, pending completion of Task Force activities, information gathering and development of long-range plans for the program. Since the establishment of the program, the Department has discovered that there are many groups already involved in organ transplant activities and does not wish to overlap, duplicate, or curtail existing systems with a national program. Once the Department has completed its initial data gathering efforts, we should be in a better position to develop long-range plans for the program and to propose appropriate budget and staffing arrangements.

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Question. The United Network for Organ Sharing (UNOS) currently provides a computer matching system for kidney donors and recipients funded by Medicare's End Stage Renal Disease (ESRD) program. How will awarding the contract for the Network mandated by P.L. 98-507 affect Medicare funding of UNOS?

Answer. At this point in time, we do not know how the Public Health Service's award of the Network Contract will affect the funding that the Health Care Financing Administration (HCFA) provides to UNOS. This is one of the reasons that we feel that it would be an improper exercise of our stewardship to implement the statute at this time without doing background work. The problem is that there are currently several existing networks, UNOS certainly being one of the larger ones. Therefore, we feel it is imperative to have a full understanding of how the networks that are currently in place operate so that when we implement the statute, it will be implemented in a way that will not denigrate the system or have a negative impact on existing networks. Were we not to do this, we might very well reduce the capabilities of the systems that are now in place and functioning.

Question. At the first meeting of the Task Force on Organ Transplantation, established by P.L. 98-507, representatives of DHHS stated that it was the Administration's intention not to fund the OPO grant program, the Network contract, or the scientific registry, all mandated by P.L. 98-507, until the Task Force completes its deliberations. P.L. 98-507 clearly requires immediate implementation of these programs, and further states that their implementation should not be delayed pending Task Force consideration.

Given the requirements of the P.L. 98-507, the overwhelming support in Congress for the law, and the overwhelming support among experts in the field for the prompt implementation of the law, why has your department chosen to delay implementing these programs?

Answer. Four things led us to conclude that the Task Force should provide advice on the implementation of the network.

First, a number of issues that the Task Force is mandated to address affect the network. For example, the Task Force's review of networks is implied by the requirement in the law that it assess "organ procurement procedures, systems and programs...." Other issues relating to the network that are relevant to the Task Force's consideration are: education of health professionals and the public; assuring equitable patient access and allocation of organs; identification of public and private efforts to procure human organs; and identification of barriers to donation.

Second, we need to understand, as fully as possible, network activities that are currently in place so that what is finally implemented takes full advantage of what already exists and does not denigrate the level of service that is currently available.

Third, we felt that since we had Task Force members with such outstanding backgrounds, knowledge and experience in all areas of transplantation, we should take advantage of their expertise to help assure that when the network is implemented, it will be as efficient and effective as possible.

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Finally, section 372(b)(1)(B) of the statute states that the network must "have a board of directors which includes representatives of organ procurement organizations (including organizations which have received grants under section 371), transplant centers, voluntary health associations, and the general public." (Underlining added.) Since we cannot complete regulations for the organ procurement organizations (OPO) grant program established by section 371 until the Task Force has completed its report in January 1986, it will not be possible to make grants to the OPOs so that their representatives will be available to be appointed to the board of directors of the network until after the Task Force report is completed. In view of this statutory requirement, there cannot be any bidders that would be compliant with this statutory requirement until after OPO grants have been awarded. Therefore, based on this statutory requirement, no contract award for the operation of the network can be made until, at the earliest, sometime in calendar year 1986.

In the instance of both the network and the assistance program for OPOs, please be assured that once the guidance has been provided by the Task Force and we have had an opportunity to consider it and how we should use it in implementation of the statute, we will proceed as rapidly as possible with its implementation.

The situation with the scientific registry is quite similar to the network. There are numerous registries currently in place and functioning. Once again, we feel it is important that we understand these registries and how they function so that in designing the Federal implementation strategy it will in no way denigrate or reduce the level of service and information currently available through the existing registries. It is our view that the people with the best knowledge and with access to the best information to assist us in this activity are the members of the Task Force. Here again, once we have received the advice and guidance of our Task Force and have had an opportunity to consider it and its ramifications for the implementation of the scientific registry, we will proceed to implement the registry as required by the statute.

Question. When can we expect to see the National Heart Transplantation study released?

Answer. In September 1981, the Health Care Financing Administration (HCFA) awarded a contract to Batelle Institute to review the efficiency, cost and quality of life implications associated with heart transplant surgery. Both HCFA and PHS have reviewed a draft report on the study and have provided comments to Batelle. We are still awaiting the final report. It is our understanding that Batelle had some difficulties with the data.

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SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until tomorrow at 9:30 here in Dirksen 116 when we will hear from the Health Resources and Services Administration and the Office of the Assistant Secretary for Health.

[Whereupon, at 11:50 a.m., Tuesday, March 5, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, March 6.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

WEDNESDAY, MARCH 6, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:30 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HEALTH RESOURCES AND SERVICES ADMINISTRATION

STATEMENT OF ROBERT GRAHAM, ADMINISTRATOR

ACCOMPANIED BY JAMES A. WALSH, ASSOCIATE ADMINISTRATOR FOR OPERATIONS AND MANAGEMENT

BUDGET REQUEST

Senator WEICKER. The hearing will come to order.

Today we will hear first from the Health Resources and Services Administration, which has jurisdiction over the maternal and child health block grant, community health centers, a variety of programs delivering health care services for underserved groups, as well as health professions and nurse training programs.

For fiscal year 1986, Congress provided $1.5 billion for these programs. The budget request for the agency for fiscal year 1986 totals $1.1 billion. All health professions and training programs of any sort would be eliminated.

I look forward to hearing from Dr. Robert Graham, Administrator of the agency, on what I hope will be a very interesting explanation for what I have indicated already as the elimination of all health professions training programs.

Dr. Graham, why don't you introduce your colleagues and proceed any way you want.

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INTRODUCTION OF ASSOCIATES

Dr. GRAHAM. Mr. Chairman, thank you very much.

With me at the table is Dr. James Walsh, who is my Associate Administrator for Operations and Management. I believe we will also be joined at the table during this session by Mr. Dennis Williams, who is the Acting Deputy Assistant Secretary for Budget in the Department. Behind me there are also directors of other bureaus.

Senator WEICKER. Is Mr. Williams here? Does he want to join you now?

Dr. GRAHAM. I don't believe he is here yet. He will join us when he arrives.

Also in the room are the directors of the three bureaus whose budgets this covers: Dr. Edward Martin, Director of the Bureau of Health Care Delivery Assistance; Mr. Thomas Hatch, Director of the Bureau of Health Professions; and Dr. Daniel Whiteside, Director of the Bureau of Health Maintenance Organizations and Resources Development.

I may from time to time, as we get into the questions that you have, ask them to provide further explanation on the specific points.

PREPARED STATEMENT

I would ask at this point in the record that my full statement be introduced. I do not propose to read it.

[The statement follows:]

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STATEMENT OF ROBERT GRAHAM

I appreciate this opportunity to appear before you today to discuss the fiscal year 1986 budget request for the Health Resources and Services Administration. As you are aware, Mr. Chairman, this budget excludes the Indian Health Service, which is reviewed by the Subcommittee on the Department of the Interior and Related Agencies.

The Health Resources and Services appropriation consists of health services, health professions and nurse training, medical facilities and health maintenance organization programs. Authorizations for most of the agency's programs expired at the end of fiscal year 1984 and were extended through the current fiscal year by the Continuing Resolution, Public Law 98-473, and the 1985 Appropriations Act, Public Law 98-619. The Administration will soon propose legislation to extend those authorizations for which funding is requested in the fiscal year 1986 budget.

The fiscal year 1986 budget request for Health Resources and Services is $1,157,393,000 and 2,381 full-time equivalent (FTE) employees. Included in this request are funds for block grants to States to provide health services to mothers and children, the poor, migrants, black lung victims and other needy Americans; to continue the health care programs of the National Health Service Corps; to operate the National Hansen's Disease Center; to provide the Federal payment to Hawaii for treatment of persons with Hansen's disease; to continue monitoring the medical facilities and health maintenance organization loan portfolios; and to manage the Health Educational Assistance Loan program.

Health Care Delivery and Assistance

In 1986, $478,000,000 is requested for the Maternal and Child Health Block Grant, the same amount as was appropriated in 1985. These funds will provide consolidated grants to each of 57 States and insular areas to provide a broad range of health services, including preventive care, primary care and rehabilitative services to mothers and children. Funds are allocated on a pro-rata percentage system. In addition, funds are provided for special projects of regional and national significance.

The Primary Care Block Grant will be expanded in 1986 to include community health centers, black lung clinics, migrant health centers, and family planning activities. The 1986 budget request provides $550,100,000 for grant awards to 50 States, the District of Columbia and Puerto Rico, and assumes the enactment of proposed new legislation. By combining categorical programs into the Primary Care Block Grant, this proposal will enable States to direct resources to the areas of greatest need while continuing to provide: primary care services; health services for respiratory and pulmonary impairments in coal miners; health services to migrant and seasonal farmworkers and their families; and family planning services to populations in need.

The 1986 budget request of $50,000,000 for the National Health Service Corps will support a total field strength of 3,507 physicians and other health professionals, including 570 Federal salaried assignees. In addition to Federal salaried field assignees, 2,937 providers will be fulfilling their scholarship

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obligations as private practitioners, an increase of 485 over 1985. Through increased reliance on private placement with non-Federal employers and the private practice option, this budget will support an increase of 405 in total field strength while permitting a decrease in Federal funding. Under private placement assignments or the private practice option, a person may complete the service obligation -- incurred while receiving a National Health Service Corps scholarship -- through private practice in a health manpower shortage area. A private practice assignment requires no direct Federal salary support and thus provides needed service at less expense to the government.

In 1986, 1,414 scholarship obligors will be available for service for the first time. Of these, 190 are estimated to elect the private practice option and 974 will choose to serve in private placement settings. About 250 will become Federal employees -- 120 with the National Health Service Corps and 130 with the Indian Health Service.

The budget request includes $18,694,000 for: the continuation of patient care, medical education and research activities at the National Hansen's Disease Center; for Hansen's Disease contract patient care; for payments to survivors and dependents of the Tuskegee Syphilis Study; and $750,000 for routine recurring repairs and improvements at the National Hansen's Disease Center at Carville, Louisiana. Also requested is $2,500,000 for payments to the State of Hawaii to partially support the cost and treatment of persons with Hansen's disease; and $27,265,000 to manage and operate all programs of the Bureau of Health Care Delivery and Assistance. Beginning in 1986, total costs for the Federal Employee Occupational Health program will be met on a reimbursable basis; therefore, no program funds are requested to support the 85 reimbursable FTEs needed to carry out this function. Requests for consultation services, formerly funded by direct appropriation, will be billed to user agencies, and the program's health unit operations will be assumed by the agencies they serve. The total budget request for the Bureau's health service programs is $1,127,309,000 and 1,773 FTEs, excluding 85 reimbursable FTEs.

Health Professions

Federal efforts to support the health professions have resulted in long term trends of steadily increasing supplies of physicians, nurses and other health professionals and an improvement in the distribution of health care practitioners among the medically underserved areas of the country. Recent HHS data indicate that there has been a 16% decrease in the number of primary care health manpower shortage areas between December 31, 1983, and September 30, 1984, and a 24% decrease in the number of primary care physicians needed in these areas. Most health professions disciplines are projected to have an excess supply by 1990. At the same time, cumulative Federal contributions to health professions and nursing student assistance funds, combined with Health Education Assistance Loan guarantees, have put in place a foundation of Federal health professions student aid which will amount to approximately $167 million in 1986. Consequently, programs providing general support to health education designed to increase the numbers of practitioners are no longer needed.

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In recognition of these trends, the Administration proposes discontinuation of health professions education subsidies in fiscal year 1986. The FY 1986 request includes $2,720,000 and 68 FTEs for direct operations to conduct the close-out of programs funded in fiscal year 1985 and to administer the Health Education Assistance Loan program and maintain the Health Professions and Nursing Student Loan revolving funds in FY 1986. The budget also requests authority to guarantee up to $100,000,000 of loans under the Health Education Assistance Loan program.

Health Maintenance Organizations and Resources Development

The budget request for the Health Maintenance Organizations and Resources Development programs for fiscal year 1986 is $15,512,000 and 245 FTEs. These funds provide $1,200,000 to pay interest subsidies on guaranteed loans to health teaching facilities and $14,312,000 for direct operations. No funds are requested for Health Planning programs, consistent with the Administration's intent to eliminate unnecessary and burdensome Federal regulatory involvement in State and local health planning activities.

Direct operations funds will be used to: monitor approximately $1.0 billion in outstanding health facility loans and loan guarantees in order to minimize Federal default liability; monitor more than 4,500 health facility construction grants, recovering Federal funds when required and ensuring that facilities which previously received Federal funding comply with requirements to provide a reasonable level of uncompensated care to persons unable to pay; monitor over 600 grants and loan guarantees valued at more than $1.4 billion made to health education facilities; evaluate Health Maintenance Organizations (HMOs) to determine whether they meet all requirements for Federal qualification; evaluate competitive medical plans to determine their eligibility to contract with the Health Care Financing Administration to provide care for Medicare beneficiaries; monitor qualified HMOs, including those with Federal loans and loan guarantees, to assure continued compliance with all Federal regulatory requirements; and administer a program designed to promote energy conservation and cost savings by health facilities.

In addition, $25,000,000 is requested for the Medical Facilities Loan and Loan Guarantee Fund. The $25,000,000 requested in new budget authority, along with approximately $5.8 million in prior year unobligated funds and repayments of principal and interest, will be used to meet the total interest subsidy requirements of $30,800,000 in FY 1986.

Program Management

The Program Management request of $11,852,000 and 210 FTEs provides operational resources for the Office of the HRSA Administrator. This office provides leadership and support for a variety of agency-wide management and support functions including short and long-range program planning, evaluation, policy coordination, management of personnel, financial management, procurement, and management systems. The request would also provide resources for the Facilities Engineering functions transferred to HRSA in fiscal year 1984.

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Thank you for providing me with the opportunity to summarize the Health Resources and Services Administration budget for 1986.

Mr. Chairman and members of the Committee, I will be pleased to answer any questions you may have on the specifics of this budget request.

Biography of Robert Graham

BIRTHPLACE : Pueblo, Colorado

DATE OF BIRTH: FEBRUARY 15, 1943

EDUCATION : Earlham College, Richmond, Indiana; A.B. Degree, 1965

University of Kansas School of Medicine; M.D. Degree, 1970

Resident in Family Practice, Baptist Memorial Hospital, Kansas City, Missouri, 1974-1975

PROFESSIONAL ACTIVITIES

1. September 1982 - Present
   Administrator, Health Resources and Services Administration, Department of Health and Human Services, and

   Assistant Surgeon General, U.S. Public Health Service

2. January 1981 - August 1982
   Acting Administrator, Health Resources Administration, Department of Health and Human Services

3. July 1979 - December 1980
   Professional Staff Member, Subcommittee on Health and Scientific Research, Committee on Labor and Human Services, United States Senate

4. July 1978 - 1979
   Deputy Administrator, Health Resources Administration, Department of Health Education and Welfare, and

   Executive Secretary, Graduate Medical Education National Advisory Committee (GMENAC)

5. July 1976 - July 1978
   Deputy Director, Bureau of Health Manpower, Health Resources Administration, Department of Health Education and Welfare

6. January 1976 - June 1976
   On staff of Program for Health Management, Baylor College of Medicine, Houston, Texas, and

   Instructor, Department of Community Medicine, Baylor College of Medicine, Houston, Texas

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7. February 1973 - January 1976
Assistant Director, Division of Education, American Academy of Family Physicians, Kansas City, Missouri, and Administrative Officer, Society of Teachers of Family Medicine

8. June 1970 - February 1973
Assistant Administrator for Agency Goals, Health Services and Mental Health Administration, Department of Health Education and Welfare, Washington, D.C.

9. 1970-1973; 1976-Present
Commissioned Officer, Active Duty, United States Public Health Service; Assistant Surgeon General, September 1982 -

APPOINTMENTS

1. Member, Secretary's Task Force on Black and Minority Health, Department of Health and Human Services, 1984

2. Chairman, White House Task Force on Meharry Medical College, 1982

3. Member, National Board of Medical Examiners (Federal Representative), 1981-1982

4. Consultant, National Academy of Sciences/Institute of Medicine, Social Security Studies, 1974-1976

5. Advisor, Robert Wood Johnson Foundation, Rural Practice Project, 1975-1979

6. Student Consultant, Carnegie Commission on Higher Education, 1969-1970

ASSOCIATIONS

1. American Academy of Family Physicians, 1973 -

2. American Medical Association, 1970 -

3. Association of American Medical Colleges, 1968 -

4. Society of Teachers of Family Medicine, 1973 -

5. Society for Health and Human Values, 1969 -
(Member, Executive Council, 1971-1975)

SELECTED RECENT PUBLICATIONS

1. "The GME Quandary: Who Will Pay for the Piper's Lunch?"; Graham, R.; Public Health Reports, Vol. 99, Nos. 1-3, Jan.-Feb., 1984.

2. "The United States Health Care System"; Graham, R.,; Textbook of Family Practice, 3rd Edition, 1983.

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3. "The Federal Role in Health Professions Education,"; Graham, R. Bulletin New York Academy of Medicine, Vol 59, No. 6, July-August, 1983.

4. "Policy Implications of the National Study of the Content of Family Practice,"; Graham, R.,; The Journal of Family Practice, Vol 15, No. 4, 1982.

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HEALTH RESOURCES AND SERVICES

[Dollars in thousands]

	Fiscal year—				
	1984 actual appropriation	1985 President's budget amendment	1985 appropriation and continuing resolution	1985 revised request	1986 President's budget
HEALTH CARE DELIVERY AND ASSISTANCE					
MCH block grant	$399,000	[1]$407,000	$478,000	$478,000	$478,000
(FTE's)	(10)	[1](10)	(10)	(10)	(10)
Primary care block grant	1,228	[1]533,400	547	547	550,100
Community health centers	350,122	.....	359,453	[2]374,453	.....
Black lung clinics	3,120	.....	3,300	3,300	.....
Migrant health	42,000	.....	44,300	44,300	.....
Family planning	140,000	.....	142,500	142,500	.....
Subtotal, primary care	536,470	[1]533,400	550,100	565,100	550,100
Home health	5,000	0	3,000	3,000	0
National Health Service Corps	[2]68,152	67,174	75,000	[3]59,438	50,000
(FTE's)	(1,344)	(1,054)	(825)	(746)	(884)
National Health Service Corps Scholarships	6,300	0	2,300	2,300	0
Hansen's Disease Center	18,449	18,694	18,694	18,660	18,694
(FTE's)	(384)	(384)	(384)	(384)	(384)
Federal employee occupational health	1,219	0	600	595	0
(FTE's)	(26)	(0)	(13)	(13)	(0)
Payment to Hawaii	2,200	1,905	2,500	2,500	2,500
Direct operations, BHCDA	42,164	[4]21,793	43,000	42,865	27,265
(FTE's)	(832)	[4](410)	(832)	(812)	(495)
Subtotal, BHCDA	1,078,954	1,050,266	1,173,194	1,172,458	1,126,559
(FTE's)	(2,596)	(1,858)	(2,064)	(1,985)	(1,773)

See footnotes at end of table.

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HEALTH RESOURCES AND SERVICES—Continued

[Dollars in thousands]

	Fiscal year—				
	1984 actual appropriation	1985 President's budget amendment	1985 appropriation and continuing resolution	1985 revised request	1986 President's budget
HEALTH PROFESSIONS					
Health professions student assistance:					
Student assistance for the disadvantaged	0	5,000	0	0	0
EFN scholarships	5,600	0	7,000	7,000	0
Subtotal	5,600	5,000	7,000	7,000	0
Health professions institutional assistance:					
Financial distress	5,600	4,188	5,600	5,600	0
Health promotion/disease prevention:					
Public health capitation	4,838	0	5,00	5,000	0
Public health/health administration special projects	0	2,000	0	0	0
Health administration grants	1,440	0	1,500	1,500	0
Public health traineeships	2,569	0	3,000	3,000	0
Health administration traineeships	480	0	500	500	0
Preventive medicine residencies	1,600	1,000	1,600	1,600	0
Subtotal	10,927	3,000	11,600	11,600	0
Primary care:					
Family medicine/general dentistry R&T	34,000	20,000	36,000	36,000	0
General internal medicine and pediatrics	17,500	9,500	18,500	18,500	0
Family medicine departments	7,790	5,000	7,500	7,500	0
Physician assistants	4,462	0	4,800	4,800	0
Subtotal	63,753	34,500	66,800	66,800	0
Health profession special education initiatives	3,262	3,000	8,000	8,000	0
Area health education centers	17,920	10,000	18,000	18,000	0
Special initiative — Pacific Basin	0	0	2,500	(*)	0
Disadvantaged assistance	18,188	24,000	24,000	24,000	0
Health profession analysis studies and reports	3,000	2,000	2,000	1,720	0
Nurse training:					
Advanced nurse training	13,260	1,300	16,500	16,500	0
Nurse practitioner	11,760	3,000	12,000	12,000	0
Special projects	7,156	8,000	9,500	9,500	0
Traineeships	9,600	0	11,500	11,500	0
Fellowships	960	0	2,000	2,000	0
Research grants	9,000	2,000	9,400	9,400	0
Loan repayments and cancellations	330	0	0	0	0

See footnotes at end of table.

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HEALTH RESOURCES AND SERVICES—Continued

[Dollars in thousands]

	Fiscal year—				
	1984 actual appropriation	1985 President's budget amendment	1985 appropriation and continuing resolution	1985 revised request	1986 President's budget
Nurse training—Continued					
Nurse anesthetists	400	0	800	800	0
Center for Nursing Research	0	0	5,000	[6]5,000	0
(FTE's)	(0)	(0)	(40)	(0)	(0)
Subtotal	52,466	14,300	66,700	66,700	0
(FTE's)	(0)	(0)	(40)	(0)	(0)
Health education assistance loans	([1])	(175,000)	([1])	([1])	(100,000)
Direct operations	[2]20,446	15,305	20,000	19,838	2,720
(FTE's)	(329)	(288)	(329)	(326)	(68)
Subtotal, BHPr	201,161	115,293	232,200	229,258	2,720
(FTE's)	(329)	(288)	(369)	(326)	(68)
HMO AND RESOURCES DEVELOPMENT					
Local planning	37,731	0	[3]37,731	37,731	0
State planning	19,200	0	[3]19,200	19,200	0
Planning methods development	1,325	0	[3]1,325	1,325	0
Health teaching facilities	800	1,200	[3]1,228	1,228	1,200
Direct operations	[2]20,544	12,335	[3]20,544	20,318	14,312
(FTE's)	(369)	(232)	(369)	(365)	(245)
Subtotal, BHMORD	79,600	13,535	[3]80,028	79,802	15,512
(FTE's)	(369)	(232)	(369)	(365)	(245)
Buildings and facilities	883	0	0	0	750
Program management	[2]24,926	8,025	22,300	21,389	11,852
(FTE's)	[4](408)	(154)	(363)	(307)	(210)
Total, HRS	1,385,524	1,187,119	1,507,722	[12]1,502,907	1,157,393
(FTE's)	(3,702)	(2,532)	[13](3,165)	(2,963)	(2,296)

[1]The MCH and primary care block grants were contained in the OASH fiscal year 1985 President's budget request, but are shown here for comparability purposes.

[2]Reflects a reprogramming of $18,281,000 within HRS and an appropriation transfer of $4,567,000 to other appropriations.

[3]Reflects a reprogramming of $15 million to community health centers from the National Health Service Corps.

[4]Includes $1 million and 20 FTE's to administer the two block grants which were in the OASH fiscal year 1985 President's budget request, but are shown here for comparability purposes.

[5]Reflects a proposed appropriations transfer to human development services for foster care and adoption assistance claims.

[6]Appropriated in fiscal year 1985 but not available for obligation due to lack of authorizing legislation and will lapse.

[7]No limit provided in appropriations language.

[8]Includes transfer of $1,401,000 from program management for central services costs.

[9]Provided under continuing resolution (Public Law 98-473).

[10]Includes transfer of $1,598,000 from program management for central services costs.

[11]Excludes transfer of $2,999,000 to BHPr and BHMORD for central services costs. Includes $9,992,000 and 156 FTE's for facilities engineering comparatively transferred to HRS in fiscal year 1984.

[12]Includes $587,000 proposed to be withheld from obligation, and would lapse, as required by section 515 of the Treasury-Postal Service Appropriations Act, 1985 (Public Law 98-473).

[13]Reflects FTE's resulting from the effect of the 1985 appropriation.

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MEDICAL FACILITIES GUARANTEE AND LOAN FUND

[Dollars in thousands]

	Fiscal year—				
	1984 actual appropriation	1985 President's budget revision	1985 appropriation and continuing resolution	1985 revised request	1986 President's budget
Interest subsidy payments	32,000	[1]26,500	[1]26,500	[1]26,500	[2]25,000

[1]An additional $5.5 million would be transferred from the "Direct loan" account in this fund to provide the total estimated $32 million required for interest subsidy payments in fiscal year 1985.
[2]An additional $5.8 million would be available from prior year unobligated funds and repayments to meet total estimated $30.8 million required for interest subsidy payments in fiscal year 1986.

HEALTH PROFESSIONS TRAINING PROGRAMS

Dr. GRAHAM. As you have indicated, we are proposing in fiscal year 1986 the discontinuation of health professions assistance programs. We are proposing the block grant in the primary care area, consolidation of several areas which now function as special project programs, continuation of the maternal and child health programs, continuation of the National Health Service Corps, and discontinuation of the Health Planning Program.

I believe those are the highlights of the budget. I would like to use the rest of our time to discuss those issues with you.

Senator WEICKER. Why don't you give me first of all your reasoning for eliminating all the health professions training programs.

Dr. GRAHAM. I think what that reflects is an assessment of the priorities within the finite set of Federal resources. The health professions programs were enacted by the Congress largely beginning in the 1960's when there was a general perception that we had an across-the-board shortage of all types of health professions: doctors, dentists, nurses, and any other type of health professionals you might indicate. As a result of that, the Federal Government became heavily involved in increasing the capacity for training those health professionals, expanding school sizes, building new facilities, and providing scholarships.

Now, though, in the mid-1980's we find ourselves in a totally different environment where rather than looking at shortages, we are looking at surpluses. I think within that environment the feeling is that to continue a Federal subsidy for the training or the expansion or maintenance of the capacity of this system does not stand up with the other priorities that we have for Federal expenditures.

SUPPLY OF HEALTH PROFESSIONALS

Senator WEICKER. There are surpluses of health professionals in rural areas? There are surpluses of health professionals in the inner city, a surplus of health professionals in areas such as Appalachia?

I don't have the statistics with me, but I didn't realize we had a surplus.

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Dr. GRAHAM. You are starting to see some marked changes in the supply of health professionals in all parts of the United States, and some of those that you have mentioned. The supply of physicians in the United States today is roughly 500,000 practicing physicians. The supply in 1997 or 1998 will be 700,000 practicing physicians. On top of the physician supply we have today, we will increase that supply by 40 percent.

Senator WEICKER. Let's go over those statistics again. You have how many practicing physicians now?

Dr. GRAHAM. 500,000.

Senator WEICKER. By what year are we going to be enjoying this additional number?

Dr. GRAHAM. The late 1990's; 1997, 1998.

Senator WEICKER. What is going to happen if physicians don't die or retire?

Dr. GRAHAM. Unfortunately, they do both.

Senator WEICKER. So what are we talking about here?

Dr. GRAHAM. What we are talking about is that the cohort of physicians that are eligible for retirement or may die is a cohort of physicians that were trained in the 1940's and 1950's. That is the time during which the United States was training only some 5,000 to 6,000 physicians a year.

Today we graduate 18,000 physicians every year. That means that for every 5,000 to 6,000 that may leave practice, 18,000 join practice. That is why the curve is going up so rapidly.

ADEQUACY OF SUPPLY

Senator WEICKER. I don't mean to get into all the details of your profession, but it seems to me that they also engaged in a great deal more specialization during that period of time. Indeed, the care given is far better than it used to be in terms of individuals that concentrate on one area of medicine.

It seems to me that I read about 1 week ago, and I remember the newspaper, but the source of the compilation eludes me, where there were 35 million Americans totally uncared for in terms of medicine. They don't have any health insurance, health care, whatsoever—35 million. That figure was up from 27 million, which is the last count. That is the count I have been using for much of my work. The latest count is 35 million.

What is happening to these people, if you have all of these extra doctors floating around?

Dr. GRAHAM. First, whatever those figures may be, that is an area where you can get into a rather brisk debate about what the total number of Americans is that are without health care or without adequate access to services.

Senator WEICKER. Excuse me 1 minute.

Could somebody please contact my office and get that? It is a New York Times article about 1 week or 10 days ago. It specifically discusses this.

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Go ahead, Dr. Graham.

Dr. GRAHAM. But I think it is a useful approximate measure to separate out some of the issues we are talking about. The question you have raised is the aggregate supply of doctors. The second question you have raised is the effective supply, or people getting care.

Indeed, you can find in Washington, DC, which has one of the highest physician-population ratios, pockets of individuals where the care is probably what you and I would both agree is not adequate. Simply turning out additional numbers of physicians does not appear to necessarily answer all the problems or all the issues that we have in providing access to services.

We run the National Health Service Corps. We have seen profound changes in our ability for assignment of the National Health Service Corps obligors over the last 5 years because the number of health manpower shortage areas, which is the indication of the ratio of physicians to population, is shrinking.

You asked if 700,000 physicians are going to be physicians in rural America, Appalachia, or the inner city. The answer that we can give you now is that those patterns are developing. I would never tell you that with 700,000 physicians or with 1,400,000 physicians every part of the United States is going to have a physician the way that population might wish to have a physician. There are some parts of the United States where it probably is not possible to build a viable medical practice.

My background is in family practice. I come from the Midwest. I know there are parts of Kansas, Wyoming, Montana, where no matter how many physicians we have, towns that had doctors back in the 1900's are not going to have doctors now because you just can't support the modern technological practice with a town of 250 or 300 people.

However, what we are talking about is the adequacy of supply and whether or not there is a compelling need for continued Federal subsidies to maintain that level. What we are reflecting in this budget request before you is our assessment that in terms of relative priorities of Federal expenditures, it is no longer a high enough priority to require Federal funding.

MATERNAL AND CHILD HEALTH PROGRAM

Senator WEICKER. You know, I have to sit here year after year, and especially this year, with some of the cuts that are made, and it is a long, protracted, pulling and hauling, a few million dollars for this program and that program that I am told because of our priorities in our budget we have to cut. I sit as No. 2 person on the Defense Subcommittee. We pull out billions and billions, just like that. Don't worry; billions, billions. They are all part of this operation, many of your professionals. You all ought to go to work for David Stockman and get out of what you are doing now. If you are a budget expert, that is fine. But doctors and physicians and experts in the health field, this is the advocacy, and half of the American people are in areas where you are supposed to help the advocacy and help the country.

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The budget request calls for level funding of the Maternal and Child Health Program—$478 million, as we appropriated last year. Within their funding, as you know, 15 percent is set aside for discretionary grants. This year a total of 420 projects will be supported, 60 more than in fiscal year 1984. These have been lauded for the fine work they are doing in areas such as infant mortality and low birthweight, improving services for high risk mothers and infants, and improving the health status of handicapped infants and children.

Your proposal would hold these funds at the 1984 level, thereby eliminating these 60 projects and reducing the set-aside for these programs by some $12 million below the 1985 level.

Why would you propose this reduction when the amount available for allotments to the States increased considerably from 1984 to 1985 and when these programs funded by the set-aside are doing such fine work?

Dr. GRAHAM. There is no question that we feel that the programs funded under the SPRANS project are doing a very good job. It is a matter of our assessment of where those moneys may be best used.

We are trying to maintain a balance between the funds available for the SPRANS types of activities and the funds available to the States under the block grant mechanism to provide direct care services.

It has been our judgment that the best balance is to be maintained by providing the dollar level for the SPRANS activity that was achieved in fiscal year 1984.

INFANT MORTALITY

Senator WEICKER. The recent report on "Hunger in America" cites three studies which reveal ways in which an infant's health is compromised by poor maternal nutrition. We know the risks, including the fact that low birthweight is now the eighth leading cause of death in the United States. How do you see a freeze in the Maternal and Child Health Program aiding this problem?

Dr. GRAHAM. The issue of infant mortality and what we can and what we should do about it is probably one of the most complex that we will discuss this morning.

We are working very hard with the MCH Program, the Community Health Center Program, the National Health Service Corps, and with State and local health agencies to identify what the trends and patterns are on infant mortality, prenatal care, and to provide all possible assistance, whether that be technical or the dollars available to us under the budget, to the local entities and local practitioners that have the responsibility for providing the necessary prenatal and infant care. We do feel it is possible for us to continue with these initiatives.

Senator WEICKER. Last year we asked you again to report on what progress we are making in the effort to reduce infant mortality. You explained that "The trend line for infant mortality overall in this 1 additional year of data that we have continues to be down."

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The Institute of Medicine and other recent studies indicate that the decline in infant mortality has slowed significantly in the past year and a half. Also, it appears that the incidence of low-weight births has declined only moderately. The Children's Defense Fund study projects that we will come nowhere near the goal set in 1978 by the Surgeon General to reduce infant mortality to 9 per 1,000 live births by 1990.

My questions are as follows: Within the context of the maternal and child health block grant, what action could be taken to get the rate of progress on a faster track, and what amount of money would be required to lower the national infant mortality rate to 9 per 1,000 live births by 1987, particularly in those seven States with the highest rate?

Dr. GRAHAM. What we are already doing through the Maternal and Child Health Office and those other programs that I mentioned to you is putting together what we believe to be an effective strategy of using Federal, State, and local resources for providing consultation to those areas and municipalities where there are identified major problems in the infant mortality patterns.

I don't know that it is possible to put a dollar figure arbitrarily on what would be necessary to assure that we will reach the targets that are set out for infant mortality in 1990. What we seem to be learning now is that some of the gains that we have been making during the late seventies and early eighties have been gains because of the application of technology and that we have been able to save a proportionately larger and larger number of children that were born at unusually low birthweights.

The number of children or the increasing proportion of children that can be saved because of the application of technology may be diminished because we are reaching the limits of elasticity of what our technology can do to assist those infants. That means the area where we are going to have to improve our efforts is going to be in areas that may be more behavioral than they are strictly medical.

I don't know how much money it takes to get young teenage women who become pregnant not to smoke. I don't know how much money it takes to get young teenage women who become pregnant not to drink or not to take drugs. I am not sure that it is possible to give you just a dollar figure and say if we had that number of dollars available, young people would decide not to get pregnant, would take precautions so they didn't get pregnant, or would take care they didn't get pregnant again, or wouldn't drink or wouldn't smoke or wouldn't use drugs when they are pregnant.

These are the areas where we probably are going to have to find ways to intervene with the educational system in the communities, and with the young people, to limit those risk factors. Those are the areas where it appears to us that the next major gains must be made to continue to keep that curve coming down.

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PRENATAL CARE

Senator WEICKER. Certainly wouldn't you include in that prenatal care?

Dr. GRAHAM. Obviously. And we are doing it.

Senator WEICKER. The funds for prenatal care have taken a nosedive in this administration. It is nowhere near the funds available for prenatal care that there used to be.

Dr. GRAHAM. The Federal Government is not the only source of funds for prenatal care. There are changes in the budget that reflect different strategies and investment in prenatal care in this administration, but that is one of the areas where we are trying to work with the States and counties and cities to put together a set of strategies to try to make sure that adequate prenatal care is delivered.

COMMUNITY HEALTH CENTERS

Senator WEICKER. Last year you told us of the good work being done by community health centers to lower per capita hospital admission rates and that total Medicaid reimbursements were significantly lower for community health center users than for nonusers. In addition, the centers proved to save the Medicaid system money. This is an example we can point to as to how we spend a nickel and save a dollar.

I directed a letter to the Secretary a few weeks ago which focused on the testimony last year of Janet Stern of the Southwest Neighborhood Health Center in Bridgeport.

As Mrs. Stern pointed out, the average base grant award of the centers is falling in spite of the fact that the appropriation has increased and the number of people receiving services has tripled over the last 4 years.

In addition, you have recently initiated a number of policies which have changed significantly the criteria used in the past for judging the efficiency of health centers. Also, in previous years and again last year the Appropriations Committee has included report language directing the Department to maintain current services at existing centers before commencing new or expansion activities.

Have you purposely adopted policies to keep health centers off balance and in a state of quandary about their funding and operating procedures?

Dr. GRAHAM. No; we have not. We reviewed your letter very carefully and Dr. Martin would be happy to provide you with some details in response right now, if you would like.

Dr. MARTIN. I think, Senator, with regard to the base grant questions you raised in your letter, we have always gone through a reassessment of each base grant. In the case of the aggregate numbers of dollars being available for operations in health centers, there has been a very substantial increase over the last 3 or 4 years, from $556 million in 1980 to in excess of $693 million in 1983.

The questions in the letter which you were very concerned about had to do with the strategy that we were utilizing in the context of the out-

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years. What we were really trying to do with health centers, I think, could best be stated in two responses.

One, with regard to the medical lab, x ray, and pharmacy areas, we are continuing, as we have done over the last 10 years, to work to assure that those particular services are provided at the highest quality, by the best physicians, in such a way that reflects the best current medical care we can provide.

Second, in the other areas, we are looking very critically at the best cost benefit for those dollars.

Specifically with regard to centers like southwest Bridgeport, with which, as you know, we are well acquainted, the actual number of dollars being spent by the center over the last 2 or 3 years has significantly increased. I think that is true of most of the health centers in the country.

The statement that each center is only receiving more dollars if it could do things more effectively is true. But no strategy we have within the bureau, the agency, or within the Public Health Service is meant to be disruptive.

There are various challenges in the delivery of health services in many communities across the country that we are having to aggressively deal with. For example, in Connecticut specifically, we have a differential Medicaid reimbursement for the same services between the $10 and $42 range. That kind of problem is the kind of problem we have to tackle aggressively with regard to good clinical and administrative management.

GRANT AWARDS TO COMMUNITY HEALTH CENTERS

Senator WEICKER. The testimony of Mrs. Stern indicated that their average base grant has gone from $434 million in fiscal year 1979 to $428 million in fiscal year 1984. The appropriation for the same period of time has gone from $258 million to $337 million.

Dr. MARTIN. Senator, I can submit the exact numbers.

Senator WEICKER. I am sorry; $434,000.

Dr. MARTIN. I can submit the exact figures for the record, but it is my recollection that her grant in 1980 or 1981—and this I think is a paradigm of a much larger question—was closer to $178,000 to $188,000, Federal dollars; just Federal dollars. Now I think it is in excess of $280,000. But I think we can supply those for the record.

[The information follows:]

The table below provides information on funding for the southwest Bridgeport community health center including total operating budget and Federal grant subsidy for the years 1980 through 1984

	1980	1981	1982	1983	1984
Base total	$315,677	$328,876	$357,860	$503,456	$578,087
Grant total	168,054	179,100	216,446	240,690	289,690

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INDIVIDUAL ASSESSMENT OF GRANT AWARDS

Dr. MARTIN. I think the crucial question is answered best by saying that we think it is appropriate to individually assess each grant award at a level of services, along with the alternative kinds of resources available to the centers each year, and then to make every attempt to provide adequate dollars to continue to provide services to the patient population the grantee is serving and, in some cases, to an increasing number of patients being served.

There has been, in fact, an expansion of the Federal support and the number of people being seen by the health centers; plus, in addition, as you know, there are the National Health Service Corps physicians and support mechanisms.

Senator WEICKER. If I am not mistaken, you are trying to achieve a policy of folding this program into this categorical program, trying to fold it up, put it into a primary care block grant; is that correct?

Dr. GRAHAM. That is correct, sir.

Senator WEICKER. So certainly you have the motive for seeing that this doesn't work. And all the testimony that we get is that you are spreading this money around to the point where nobody is getting adequate funds to do the job, including the startup of new centers, et cetera.

What worries me is the inner city. This is the inner city stuff right here. This is the maternal care I was talking about.

I tell you right now, you are not going to succeed again this year. We are not going to have a program like that as long as I sit in this chair, and I am good until 1988. [Laughter.] So we might as well make this thing work. We might as well get the funding to the point where it can do the job.

Dr. GRAHAM. We think we are making this work. Dr. Martin has spent an extraordinary amount of time with the full set of community health care directors who have been in town over the last 4 or 5 days. I believe that the manner in which these funds are being expended, the strategies which are being undertaken to maximize the degree to which the Federal funds can be used jointly with State and local funds to spread a set of services within the communities that need them as broadly as possible, to serve as many people as possible, is the direction that we must go, and I think that is what we are doing.

COMMUNITY HEALTH CENTERS CUT

Senator WEICKER. Then obviously this population is declining drastically because you advocated a $15 million cut for these community health centers in 1986.

Dr. GRAHAM. That is an artifact of the reprogramming that the Congress asked us to do on a one-time base. We just carried the base forward into fiscal year 1986. The Congress, as you will recall, requested us to reprogram $15 million from the National Health Services Corps field budget into CHC's in 1985, which we have done.

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Senator WEICKER. Carol, do you have a question?

Ms. ORTEGA. Since we reprogrammed the $15 million into the community health centers last year, would they not have to absorb that decrease this year?

Dr. GRAHAM. In terms of the fact that we put the budget together based upon the CHC base rather than the CHC plus a reprogramming base, yes, there would be that offset.

CURRENT SERVICES LEVEL FISCAL YEAR 1986

Senator WEICKER. Assuming the fact the primary care block grant will be rejected, how much would be needed in dollars and positions to operate these programs at a current services level for fiscal year 1986?

Dr. GRAHAM. I would be happy to provide that for the record.

[The information follows:]

If the expanded primary care block grant proposal is not approved, the current services level for fiscal year 1986 would be as follows:

	Dollars[1]	FTE's
Primary care block grant/community health centers	$391,500,000	
Black lung clinics	3,445,000	
Migrant health	46,249,000	
Family planning	146,473,000	
Total, primary health care programs	587,667,000	
Bureau of Health Care Delivery and Assistance Direct Operations	44,365,000	802

[1] The current services were calculated assuming an inflation factor of 4.4 percent

DISTRIBUTION OF PHYSICIANS

Senator WEICKER. Senator Proxmire?

Senator PROXMIRE. Thank you, Mr. Chairman.

Dr. Graham, I am very impressed by your background. You are obviously an extraordinarily intelligent man and you are doing the best you can under the circumstances. However, I think the chairman makes a very, very telling point here. We have a serious maldistribution of our most precious asset in this country, our doctors.

I have an article here from the Washington Post of February 27 which says the number of doctors in the Montgomery County Medical Society jumped from 500 to 1,300 between 1976 and 1984. The number of doctors in the Fairfax County Medical Society increased from 220 to 700 over the same period.

Those are extraordinary increases in only an 8-year period. The article says, agreeing with what you said, that by the year 2000 there will be an excess of 145,000 doctors, according to a study commissioned by the U.S. Department of Health and Human Services. The article goes on to say:

Those facing the toughest time are the specialists, particularly cardiologists, psychiatrists, and gastroenterologists. General surgeons and internists, who represent 8 percent and 22 percent of the physician population respectively, are also facing increased competition. "We have specialists up to our eyeballs," said Schneider [president-elect of the

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Montgomery County Medical Society]. "The only way to survive is to look for a procedure that others aren't doing, so they will have more to offer."

Now the chairman is exactly right. We do have a shortage of physicians in inner city Washington, although you have a bigger concentration of physicians in Washington than in any city other than San Francisco and Portland.

In my own State of Wisconsin we have a high concentration of physicians in Milwaukee and Madison and two or three other places where they have outstanding clinics. In the rest of the State there is a terrific shortage.

I think it would be very helpful for us if you could give us a series of options. I know you are doing the best you can under the circumstances given what you have to work with. But there must be some better way of promoting a better distribution of doctors while still allowing doctors to practice freely. I am not talking about socialized medicine or putting doctors on the Federal payroll. I am talking about keeping our system of free choice of physicians and so forth.

But this is so frustrating and perplexing a puzzle for us because we have a large number of doctors and the number is growing all the time yet the increase is not solving our problem.

Dr. GRAHAM. I think you are using my argument.

Senator PROXMIRE. What do we do about it?

Dr. GRAHAM. Do you believe that continued funding through health professions is going to change that pattern?

Senator PROXMIRE. No, no; you obviously think we shouldn't go that way. But if we shouldn't go that way, what can we do to solve the problem? What are the options?

Senator WEICKER. Would the Senator yield?

Senator PROXMIRE. Yes.

PRIMARY CARE TRAINING INCENTIVES

Senator WEICKER. Most of these Federal programs with assistance given required some obligation of service in various areas, or certain of the programs do.

Dr. GRAHAM. None of them are in the specific question that led us into this discussion. I would be happy to go where Senator Proxmire is opening the question, because it is more philosophical than budgetary. The specific question was around the health professionals authorities. None of those authorities carry with them the service obligation.

In terms of your question now, it is an issue with which we are all wrestling. Traditionally in this country the Federal Government has not interposed itself into individual decisions made by practitioners of medicine or pharmacy or anything else. We have talked about incentives rather than coercion.

We have a circumstance where with these 16,000 graduates a year we would still say, and I think the medical profession at large would say, that with the balance of the numbers of people coming out of medical school, we don't have enough going into primary care as opposed to those going into other areas.

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What is the answer to that? Is that more primary care training in medical school? I don't think anybody in the room would propose that the Federal Government pass a law mandating what the medical curriculum will be. But what can be done to provide greater incentives?

Senator PROXMIRE. That is my question.

Dr. GRAHAM. Our staff in the Bureau of Health Professions is a thoughtful staff and has been dealing with these issues for 5 or 10 years. We would be happy to put together some brief thoughts.

Senator PROXMIRE. That would be very helpful.

[CLERK'S NOTE.—No material was received prior to publication.]

Dr. GRAHAM. But I would hasten to point out they are not budgetary areas, they are philosophical questions.

Senator PROXMIRE. They become budgetary issues perhaps. The question is without coercion how do we provide for better distribution of our growing medical staff, which can properly be defined now as excessive, although, as the chairman points out, there are tens of millions of people in this country not getting anything like adequate medical service.

Dr. GRAHAM. We are not in disagreement with him.

NHSC FIELD STRENGTH—FISCAL YEAR 1986

Senator PROXMIRE. In your prepared testimony, Dr. Graham, you state that your 1986 budget request will support a field strength of 3,507 National Health Service Corps physicians and other health professionals. You refer to this figure as an increase of 405 in total field strength.

On page 109 of last year's justifications reference is made to a total combined field strength of 3,583 in 1985, indicating there would be a cut, not an increase, in field strength in 1986. What caused the reduction?

Dr. GRAHAM. I think I know the technical answer to that, but Dr. Martin is closer to the question, if he would respond.

Dr. MARTIN. There are two factors, Senator. One is our continuing disappointment in the percentage, 8 to 10 percent of the individuals with those kinds of obligations—this is the one health professions program that does have an obligation for service—who choose not to fulfill their contractual obligations to the Federal Government and go into service. That accounts for about 100 individuals.

The other difference was a change in policy from last year to this year to very strongly encourage physicians to complete their training. In 1984, we had in excess of 400 people with only 1 year of postgraduate training go into service. This year the agency took the position that we wanted them to complete their training in internal medicine, pediatrics, family practice, and we encouraged them very strongly to be deferred for that training. That resulted in over 75 percent of the difference between the projections.

These individuals will be coming into service in 1988–89 and will be much better trained, and the probability of their staying in those areas will be much greater.

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Senator PROXMIRE. I will ask Tom van der Voort to ask a followup.

GRADUATE DEFAULTS

Mr. VAN DER VOORT. If 8 to 10 percent of your graduates are refusing to honor their obligations, that seems extraordinarily high. I am just wondering if the Bureau is taking any steps to deal with that problem.

Dr. GRAHAM. That is the going-in number. In other words, that is the number when 1985 comes up on the calendar, they tell Dr. Martin and his staff, "Well, it may not be convenient for me to go where the taxpayers tell me to go. I will see if you can make me." There is then an administrative due process procedure when we inform them what they owe the Government and they are in default and they can pay that off. Since that is a triple penalty plus interest, some of them then see the light and come back and say, "Well, maybe I will serve after all." Some of them don't and are not able to pay it off and we wind up going to the Justice Department.

The Justice Department has become increasingly willing to take these cases to court, and to date we have not lost a case.

Senator PROXMIRE. Can you give us a report on how many individuals you have taken to court with all the relevant statistics, so we can get a feel for what you are doing to meet the problem?

Dr. GRAHAM. We would be happy to.

Senator PROXMIRE. Because the Justice Department does well sometimes, but sometimes I find they don't follow up.

Dr. GRAHAM. They are becoming increasingly helpful to us.

Senator PROXMIRE. Going from 1 percent to 3 percent of the cases?

Dr. GRAHAM. I wouldn't want to be that harsh. But 300 percent, or something like it.

[The information follows:]

CASES SENT TO THE DEPARTMENT OF JUSTICE

Status	Debtors	Principal	Interest	Judgment amount
ACTIVE				
No DOJ action to date	38	$1,875,273.07	$1,395,619.05	NA
Complaint will be filed	13	311,186.64	227,506.98	NA
Complaint filed	49	1,860,377.31	1,193,084.55	NA
Prejudgment agreement—paying—not compromised	8	136,851.50	43,069.37	NA
Prejudgment agreement—paying—compromised	3	70,532.00	42,398.83	NA
Prejudgment agreement—not paying (payment to begin at later date)—not compromised	6	115,845.01	50,069.37	NA
Prejudgment agreement—not paying—compromised	7	69,234.00	51,011.01	NA
Consent judgment—paying—not compromised	6	110,404.78	44,424.04	$121,731.97
Consent judgment—not paying—not compromised (awaiting remedial action(s) to be taken)	7	135,724.12	56,224.54	201,110.00

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CASES SENT TO THE DEPARTMENT OF JUSTICE—Continued

Status	Debtors	Principal	Interest	Judgment amount
ACTIVE—Continued				
Consent judgment—paying—compromised	1	$22,021.00	$9,586.08	$22,021.00
Consent judgment—not paying—compromised				
Default judgment—paying	2	36,224.20	9,677.23	45,901.43
Default judgment—not paying	10	253,382.12	139,621.70	404,220.87
Pending service placement	6	367,730.83	255,212.90	NA
Filed bankruptcy—in litigation	4	64,156.27	19,937.51	NA
Began (on duty) serving obligation	2	281,635.00	159,069.91	NA
SETTLED				
Paid in full—not compromised	10	170,288.75	64,873.74	254,491.88
Paid in full—compromised	10	219,544.75	89,349.17	186,738.99
Completed service obligation				
Discharged bankruptcy	1	22,126.64	9,319.37	NA
Death certificate	2	436,537.36	16,664.45	NA
Totals	179	6,063,587.15	3,816,030.56	1,444,536.57

PERSONNEL FOR HEALTH MANPOWER SHORTAGE AREAS

Senator PROXMIRE. Dr. Graham, 2 years ago you told this committee in a response for the record that you were considering various options to provide personnel for health manpower shortage areas in lieu of National Health Service Corps scholarships. More specifically, you stated, "Preliminary recommendations of the study group have been completed and are currently being reviewed with the Department."

Last year in response to a similar question you responded, again for the record, that the recommendations were still under consideration in the Department.

I hope you won't tell us today, 2 years later, that the Department is still considering the recommendations. In any event, where do the recommendations stand and when will final action be taken?

Dr. GRAHAM. We have in the intervening year had the opportunity to resolve many of the issues within the Department, and Secretary Heckler some 3 to 4 months ago sent a draft of what we would propose to be a loan repayment strategy to the Office of Management and Budget for consideration of submission as legislation.

The essential part of that strategy is that as we enter into the late 1980's and 1990, and we know we will continue to have health manpower shortages and people in need, we would provide the legislative or statutory mechanism to get people to go into service by offering to repay their loans, whether they be Federal loans or commercial loans, any legitimate loan. And we would do that in a specific year. The Congress and the Secretary could come to an agreement that in a given year there will be *x* number of thousand or million dollars for loan repayment, and the Secretary would say fine, for this year I want 100

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family physicians for urban practice and I want 100 family physicians for rural practice and I want 50 internists for internal practice, et cetera, and publish those in the Federal Register and say if you are interested in having all or part of your educational loans paid off for service, apply for this. That way we feel that we would get individuals at the time that they are willing to make the commitment which is much more of a known quantity. We would not run into the problem of a long pipeline where somebody takes a scholarship one year and then 7 years later they are called to service and their specialty interests have changed and their family circumstances have changed.

I am sure we will be in conversation with OMB about that legislation and about whether or not that is the approach to take. I would not anticipate that legislation being submitted for the consideration of the Congress for at least another year or so because we still have the National Health Service Corps pipeline in effect for 1 more year with a sizable number of assignees and then it starts dropping off precipitously.

I would say that if indeed there is agreement within the administration that our proposal is a proper course of action to consider, I would not anticipate it being proposed to the Congress for its consideration for at least another year or so.

DEBT COLLECTION

Senator PROXMIRE. Language was included in last year's Senate report on the Labor-HHS-Education appropriations bill directing the Health Resources and Services Administration to release the names of defaulting National Health Service Corps scholarship recipients to educational institutions and professional associations indicating a willingness and desire to participate in the debt collection process.

Have you carried out this directive?

Dr. GRAHAM. Some issues were raised by that directive. I would like to have Mr. Hatch or Dr. Martin respond to that.

Dr. MARTIN. The Department of Justice and the Department have a piece of legislation with regard to debt collection. The Department has worked out recently the regulations which will allow that activity and which include a host of aggressive means now to be published. So rather than to just release the names, the intention of the Department and the Department of Justice was to put the entire activity in the form of regulations.

Senator PROXMIRE. But you will release the names, will you not?

Dr. MARTIN. Yes, sir; the plan is to release the names.

Senator PROXMIRE. How many educational institutions and professional associations are being given the names of defaulting scholarship recipients?

Dr. MARTIN. The overwhelming bulk of the defaulters are physicians, so the predominant schools we will be dealing with will be the 150, give or take, medical schools. That is the overwhelming bulk of all the defaulters.

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Senator PROXMIRE. On page 27 of the justifications you indicate that a report is being prepared on the action taken by the Department to better coordinate the ongoing administration of the Health Education Assistance Loan Program with collection of delinquent and defaulted loans. Has that report been submitted to the committee?

Mr. HATCH. I understand it was to be delivered this week.

Dr. GRAHAM. We know it is very close. I don't know if it has been received by the committee.

LOAN DEFAULTS AND DELINQUENCIES

Senator PROXMIRE. Can you tell us briefly what steps you have taken to comply with the committee's directives regarding loans in delinquency and default under the HEAL Program?

Dr. GRAHAM. I would like Mr. Hatch to answer.

Mr. HATCH. Yes, sir; we have taken a series of actions initially as a result of an inspector general report on the HEAL Program which identified a variety of issues that appeared to be heading toward increasing the problem of default and delinquency. We have issued a series of policy memos to the schools and to the lenders advising them about some of these problems and instructing them with respect to such things as giving loans very late in the year when the individuals have not really had need for the loan at that point in time and a series of other things that they can now do to improve the management of the program right now under the current regulations.

We are also in the process of developing or revising regulations which will strengthen the regs with respect to the responsibilities of the schools and the lenders to some of the problems that were identified by the inspector general.

We are also developing, and these were included in last year's health professions legislation, some legislative modifications which would strengthen the HEAL Program.

HEALTH PROFESSIONS STUDENT LOAN PROGRAM

Senator PROXMIRE. Thank you.

Dr. Graham, last year you estimated you would be able to assist 24,500 students in fiscal year 1985 under the Health Professions Student Loan Program with an average award per student of $2,000.

On page 78 of this year's justifications you show an average award per student of $2,500 in 1985. As a consequence, you will be able to assist only 19,600 students, although the total amount available remains the same.

Can you tell us why the average loan per student has increased by 25 percent above your initial estimate?

Dr. GRAHAM. Those loans are administered by individual schools. They do have a formula which is a needs base formula that they must follow, I believe.

Senator PROXMIRE. You could not anticipate this increase in the average award per student?

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Dr. GRAHAM. No; we are finding it somewhat difficult to anticipate the pattern of increased educational costs year by year.

LAPSED FUNDS

Senator PROXMIRE. You apparently anticipate lapsing an unobligated balance of $5,587,000 in fiscal year 1985. What activities were these funds appropriated for and why were they lapsed?

Dr. GRAHAM. Let me try to answer this. I don't understand your question as to where do you identify that lapse. What page are you on?

Senator PROXMIRE. On page 11 of your justifications you refer to unobligated balance lapsing of $5,587,000.

Dr. GRAHAM. OK. There are two separate issues, sir.

One, the Congress appropriated $5 million for a nursing research activity. However, the language that accompanied that appropriation cited an authorization bill which was not accepted by the President. Therefore, we are advised by Department counsel that we have a circumstance where we have an appropriation without authorization. It is essentially an appropriation issue.

Senator PROXMIRE. Was the authorization vetoed?

Dr. GRAHAM. Yes; it was. The bill that appropriated the money was not vetoed, but the report language which was attached to that appropriations act cited an authorization bill which was moving through the Congress in parallel. That bill was not accepted by the President.

Senator PROXMIRE. What do you mean?

Dr. GRAHAM. It was a pocket veto.

Senator PROXMIRE. OK.

Dr. GRAHAM. So that the preponderance of the lapse, the rest of the lapse is as a result of the section 515 evaluation withholding, which I believe you heard about yesterday.

Senator PROXMIRE. Thank you, Dr. Graham. I have some questions for the record, if you could answer them.

Dr. GRAHAM. Yes.

TRAINING PROGRAMS FOR HEALTH PROFESSIONALS

Senator WEICKER. Last year we provided $121 million for nine small programs designed to help train students to become family practitioners, dentists, physicians assistants, and others, to provide care in pediatrics and rehabilitative medicine. Included in this $121 million is a program designed to have portions of training provided in medical personnel shortage areas: the Area Health Education Centers Program, as well as the principal Federal program directed at increasing the numbers of underrepresented minorities and other disadvantaged individuals who are interested in pursuing a health career. We provided $24 million for this disadvantaged assistance program last year. I have not yet mentioned that one of these nine programs is one which, of course, I initiated, funded at $5 million, the geriatric training initiative.

All of these nine programs described by you as a key part of the national goal of adequate health care for all Americans, from getting

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minorities into the health professions to getting doctors to locate in rural areas, are proposed for zero funding.

What would prompt such a request? Is it your view that only the rich should go to med school and that we should forget about trying to get doctors to locate in underserved areas, that we should not be concerned about whether doctors are trained in the special needs of the elderly?

Dr. GRAHAM. I think this refers to the earlier conversation that you and I had.

Senator WEICKER. We are getting very specific here.

Dr. GRAHAM. The answer is the same. We are in the circumstance where within a finite number of resources——

Senator WEICKER. Was this your decision? Has this gentleman arrived yet? Is Mr. Williams here?

Dr. GRAHAM. I don't believe he is in the room.

Senator WEICKER. I can understand why he is not in the room. [Laughter.] He probably made most of the decisions here. He is the guy we ought to have up here.

Dr. GRAHAM. I have no reason to put the spotlight on Mr. Williams. I am the representative of the administration for these discussions. It is my responsibility to do the best job that I can to explain the rationale to you.

RATIONALE FOR FUNDING DECISIONS

Senator WEICKER. I would like to know the rationale.

Dr. GRAHAM. The rationale is that at a time of finite Federal resources, a series of choices must be made as to what are the highest priorities for the expenditure of Federal funds.

Senator WEICKER. Even though that results in the death and suffering, et cetera, of large numbers of Americans?

Dr. GRAHAM. The choices which must be made are by their nature tradeoff choices.

Senator WEICKER. What I find difficult to accept is: You should be making these choices. I understand how Cap Weinberger is out there fighting for those defense dollars. But when I come up to this Department, both the Secretary and other professionals, you don't want to fight for your dollars.

Dr. GRAHAM. I am not sure that is a fair characterization.

Senator WEICKER. I think it is very fair. You are willing to go ahead and do all the dirty work and take all the blame yourself, even though Mr. Williams or Mr. Stockman are the ones who have gone ahead and done this budget.

Dr. GRAHAM. Mr. Chairman, that is the second or third time that has come up in this conversation.

Senator WEICKER. That is right.

Dr. GRAHAM. There is always some risk in lecturing the Chair. However, I must say that I, and I think the staff with me, have very strong feelings about public service.

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Senator WEICKER. Why don't you go ahead and follow through on your strong feelings dollar-wise? I don't care about your strong feelings. Dollar-wise, where are the dollars?

Let's just take a specific. It is estimated America's population age 75 and older is going to increase by 50 percent by the year 2000. Out of 122 medical schools, 2 have programs that are specializing in geriatrics.

There you have the statistics, as to what we are doing, what the problem is going to be. We start with $5 million to start moving in that direction. You know it is coming over the hill. What else do I have to give you in the way of statistics in the sense of meeting this problem? What else do you want?

Dr. GRAHAM. Mr. Chairman, perhaps we disagree, if you feel we live in an environment where no choices are necessary.

BUDGET DECISIONS

Senator WEICKER. I don't follow you. Do you want to explain that statement?

Dr. GRAHAM. What I have indicated to you is that the budget which is before you is a budget which reflects a series of decisions within a set of finite Federal resources. Those are decisions which any one of us in the room recognizes as difficult, painful, but they are a set of decisions. You may differ with the decisions and the choices. I full well understand different points of view.

Senator WEICKER. How can we differ? Let's just stick with this one area on the problem of the elderly. How can we differ on that? We don't have the personnel to handle what is going to be a major problem. Where are the personnel? Do you dispute that?

Dr. GRAHAM. I think the difference in point of view which is reflected in the budget before you is a difference in point of view of level of Federal effort and priority of that problem versus some other problems.

Senator WEICKER. What do you mean by some other problems? What are those?

Dr. GRAHAM. Do I dispute the growing elderly population is an important issue? No.

HEALTH CARE PERSONNEL

Senator WEICKER. Do you have the personnel to deal with it?

Dr. GRAHAM. Do we at the present time?

Senator WEICKER. Right.

Dr. GRAHAM. In some areas there may be those who feel we do and in others there are those who feel we don't. Do we have the possibility in the next 10 to 15 years through a whole variety of mechanisms some of which may not be Federal, to see changing patterns of education in our medical schools that will increase the numbers of individuals caring for such patients? Do we see changing patterns of education at our nursing schools without Federal mandates? Yes; that is going on today.

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Senator WEICKER. I tried to indicate that aspect of the problem, too, with 122 med schools and only 2 of them directed in such a way. And we are in the midst of it right now, so obviously nothing is being done, it is certainly not adequate.

Dr. GRAHAM. Do you believe the only person that can take care of somebody who is elderly is a geriatrician?

Senator WEICKER. I certainly don't.

Dr. GRAHAM. Good.

CARE OF THE ELDERLY

Senator WEICKER. But see what the problems are over the past several years. First of all, the fact that just within the span of, I would say 5 or 6 years, the use of mental hospitals to take care of the elderly because we don't have nursing facilities or adequate programs to encourage in-home nursing care. Then we move to nursing homes and all of a sudden we have a great deal of difficulty in regard to regulation and providing adequate care for those in the nursing home, not just vis-a-vis their being in bed and being fed and having the opportunity to engage in other activity.

I also see as a practical matter various doctors that are, because of their affinity for their patients, willing to run very close to the wind on the Medicare-Medicaid regulations insofar as having their patients in the hospital as compared to being in a nursing home or being at home, bopping between the hospital and their own home.

It is a mess. We are not prepared for it. We are prepared for it in terms of the physical facilities. We are not prepared for it in terms of the professionals, whether it is the nurses or the doctors. Here we are trying to get on top of a problem.

My job, doctor, is not to become a hero because I have solved a crisis. That is the way this town operates; it is not how I operate. I grade myself as being a good or bad legislator on the fact I never allow the crisis to take place. I don't care who knows my name or not. The less who know it, the better. My job is to anticipate what is going to be a crisis and avoid that. Yes; that takes up-front money.

I have had to sit here and fight tooth and nail for the last 4 years over early intervention money for retarded children, just a few million dollars. Because, thank God, we preserved that money, think of the hundreds of millions that are being saved as these children now are in the new state of the art as to what you do in the way of educating retarded children.

I know what you people are doing. You are going ahead and trying to show some dollar savings this year because you feel don't worry, everybody is just going to praise us for that and you are willing to accept the results in the out-years. That is where the hurt is going to really be felt. I am not willing to do that.

I am going to stand up here and say this is what we ought to do. If we have to pay for it, hey, I am for raising taxes. I don't have any problem with that. We don't carry anything on the cheek.

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No; I think that what you have done, if you don't mind my saying so, those of you who are the trustees of the Nation's health and best understand the Nation's health, you have turned over your job to the budgeteers. Believe me, you don't have to worry about OMB. They are quite adequate to the task of working on the budget. What I expect to hear from you and others is your expert opinion as it relates to the problem, the solution, whatever. But you are all going to sit there like a bunch of dummies and parrot whatever you are told by your budget officer. If that makes you feel happy within yourself, fine. It is not very helpful to this committee.

Dr. GRAHAM. Your statement offends me, and I think it offends anybody who is in public service. If you have a point of view that the Federal Government ought to be made up of individuals pursuing their own priorities and their own judgments and not accountable to the taxpayers, that is a very interesting view.

BUDGET ACCOUNTABILITY

Senator WEICKER. Hey, please, believe me, you are going to come out of this hearing as accountable to the taxpayers, a loyal servant to OMB, as a man who practices the President's policies. You are going to get an A plus on all of those scores——

Dr. GRAHAM. I think you missed my point.

Senator WEICKER [continuing]. So far as serving the population.

Dr. GRAHAM. You missed my point entirely.

Senator WEICKER. I didn't miss it entirely at all, not when you present this budget and present it with wild-eyed enthusiasm.

Dr. GRAHAM. There is a profound difference of opinion between us, sir. Every one of us before you have elected to pursue career civil service. That means we are committed to serving as best we can within that civil service, regardless of who our leadership may be. And 2 years from now you may be our leadership, and we would serve you to the best of our abilities.

Our job is not to sit here and tell you what our opinions are. We have adequate opportunity within the Department to fight our fights, give the best advice that we can, give the best professional judgment we can, and believe me, we do that, day in and day out.

But when the decision is made and the individual to whom we are accountable and for whom we work, elected by the people, says this is my budget, then my job is to reflect to you as best I can the rationale behind that budget, not my own personal opinion.

When I leave civil service, if you think that I as a private citizen have such excellent judgment and excellent insights that you want my personal opinion, you can call me back before the committee and you will have it. But that is not the job that I have elected to pursue at the present time, and it is not the job for which the taxpayers are paying me.

Senator WEICKER. I am sorry, we do have a disagreement. Quite frankly, if indeed you put yourself in the civil service category, then

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you are not obliged to any philosophy or any party. You are obliged to the facts of the situation. The facts of the situation fly totally in the face of the budget that you are presenting to me. Now that is the problem.

Dr. GRAHAM. That is the chairman's view.

Senator WEICKER. So you must be one of the new breed of philosopher-partisan civil servant.

Dr. GRAHAM. I do not regard myself as a partisan civil servant.

Senator WEICKER. I heard the statement of the Secretary yesterday.

Dr. GRAHAM. I have served in the administration of every President since Mr. Nixon, sir. I do not regard that as a partisan career.

BUDGET CUTS

Senator WEICKER. Well, the statement of the Secretary yesterday and your statements today are geared entirely, and the statement comes out again and again, within the constraint of these finite resources, the budget, balancing the budget, the deficit, et cetera. Not once have I heard from you or the Secretary these are cuts that we disagree with, that we are being told to deliver on. Rather, you are sitting here defending what is to me one of the most callous exercises I have ever seen, as long as I have been in Government. And I have been in it now 22 years, 23 years, as an elected official.

To me, this Nation has always attained its greatness by virtue of what it does for even the one. I see whole categories of Americans that are somehow in a minority position by virtue of their mind or their body or their background or their origin or whatever. They have been balkanized, just left adrift.

I said yesterday to the Secretary you shouldn't feel offended by her policy, yours. It is survival of the fittest. It is just great.

I will tell you what I will feel good about. It is after I get through with this round of civil servant politicians, whatever they are, that represent the administration, I am going to have the public in here for about 3 or 4 days, each taking 5 minutes. I know what I am going to see because I have seen it now in all the years I have sat in this chair, and even before I sat in this chair. Those are the people that you are supposed to be serving, not the President or the Secretary in a political sense. They are the ones who come in here with their infirmities and with their inability to get any help. And they don't get it from the private sector and they don't get it from the local government.

As I said before, the disappointment I arrive at is the very fact I mentioned. You are a civil servant. I can't get your judgment in terms of what is your forte, your expertise. I am getting a judgment based on factors that are totally unrelated to everything you have been trained in. You are not a budget man. Are you an economist? Are you an accountant? You are a doctor, right?

Dr. GRAHAM. Hopefully.

Senator WEICKER. I think you are probably a doctor and a damn good one. It is the fact I can't tap that and the explanation of this budget that bothers me.

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QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

I have no further questions. I have questions remaining from myself and other members of the committee for response to the record. Thank you very much.

Dr. GRAHAM. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

INFANT MORTALITY

QUESTION. What action are you taking to help States meet the goal of assuring parental care to nine-tenths of all women within the first three months of pregnancy -- a goal which 46 States will fail to meet by 1990?

Answer. We are not taking any action which invades the areas of responsibility and authority conferred upon the States through the block grant; however, we are acting in a variety of ways to provide information and assistance to the States, for example:

The PHS is helping to support wide dissemination of the recent infant mortality reports to help States and communities become fully aware of the nature and scope of the problem and encouraged to act upon it in the allocation of their block grant and other resources.

We are making available the services of expert teams which will assist States and communities in the assessment of infant mortality issues and problems.

We have given priority to improvement of State perinatal care systems in our MCH special project grant efforts, supported with funds set aside from the MCH Block Grant.

The PHS has undertaken a special initiative to increase availability of effective perinatal care in the 649 community and migrant health centers which reach many of the Nation's underserved populations.

COMMUNITY HEALTH CENTERS

Question. Last year you told us of the good work being done by Community Health Centers (CHC) to lower per capita hospital admission rates and that total Medicaid reimbursements were significantly lower for community health center users than for non-users. In addition, the Centers proved to save the Medicaid system money. This is an example we can point to as to how we spend a nickel and save a dollar. I directed a letter to the Secretary of a few weeks ago which focused on the testimony last year of Janet Skane Stern of the South-West Neighborhood Health Center in Bridgeport. As Mrs. Stern pointed out, the average base grant award of the centers is falling in spite of the fact that the appropriation has increased and the number of people receiving services has tripled over the last five years. In addition, you have recently initiated a number of policies which have changed significantly the criteria used in the past for judging the efficiency of health centers. Also, in previous years and again last year, the Appropriations Committee has included report language directing the Department to maintain current services at existing Centers before commencing new or expansion activities.

What specific steps have you taken to comply with Congressional directives to increase the base operating levels to reflect operating cost increases?

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Answer. The Bureau of Health Care Delivery and Assistance (BHCDA) of HRSA annually reviews each of the approximately 600 continuation grant applications submitted by CHCs to assure that adequate funds are provided to maintain existing health services while critically reviewing each health center's base grant level to assure that funds are spent only in the most efficient and effective manner possible. The BHCDA conducts such reviews based on a standard series of funding criteria including such administrative indicators as well as a continual review of the relative need of the population served by the health center. These individual health center reviews have been and we expect will continue to be the most appropriate mechanism to assure that health centers receive appropriate funding levels, while allowing BHCDA the management capability to utilize funds in the most prudent and cost effective manner. This process, which has been used for over 10 years, results in projects receiving increased funding level or decreased funding based solely on their need and performance.

Question. How much was added to the 1985 base operating amount?

Answer. We are not in a position to add funds to the base operating amount until we complete the assessment of each health center's base grant level to assure that funds are spent only in the most efficient and effective manner possible. The "base amount" of funds for each center is the amount of grant funds necessary to maintain the existing level of services to persons below 200% poverty level after appropriate third party and patient fee revenues have been discounted. Therefore, the assessment referred to above will determine the "base amount" for individual centers.

Question. Do you think it will be necessary for Congress to impose legislatively certain provisions to aid health centers' capacity to maintain certain basic services?

Answer. It is not necessary for Congress to impose further provisions to maintain health center capacity; the current process of revieving each center's base grant level will accomplish the same objective.

NATIONAL HEALTH SERVICE CORPS

Question. This Committee has supported the placement of National Health Service Corps (NHSC) assignees in Community and Migrant Health Centers. This policy makes sense from the perspectives of need and management.

It appears that you plan to utilize some 700 assignees for health center service in fiscal year 1985 and another 700 in fiscal year 1986. Thus far, we have allowed the reprogramming of $15 million for fiscal year 1985.

How much more will be required in fiscal year 1985 to place these 700 NHSC personnel in community health centers?

Answer. We are not requesting any additional reprogramming of FY 1985 funds from NHSC to CHCs at this time.

Question. How much more will be needed in fiscal year 1986?

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Answer. The budget proposal assumes that the States will be responsive to the issues involved in operating their programs in FY 1986.

Question. If this plan were approved, how much new money would be needed in fiscal year 1986 and how much can be reprogrammed?

Answer. Since the States will be responsible for administering these centers in FY 1986, no new money will be needed or reprogrammed.

Question. You are requesting no funding for the NHSC scholarship program because "the scholarship recipients who are already in the pipeline and subsequently obligated to serve will provide a sufficient base of health personnel to meet the essential staffing requirements of the NHSC for the remainder of the decade."

What happens after that? Without these people who serve in repayment of their loan obligation, how do you plan to get doctors and nurses to serve in rural North Dakota or inner-city Bridgeport, or any other critically underserved area?

Answer. The NHSC serves many poor populations, some in geographic health manpower shortage areas (HMSA) and others in defined population HMSAs. The NHSC has continued to provide well over a thousand new health professionals to these areas each year. With the decline of a scholarship program, these numbers will decrease after 1986. Likewise, due to the rapidly expanding pool of physicians in a competitive marketplace, the numbers of HMSAs are decreasing. This is due to the effects of diffusion throughout the country. Recent HHS data indicate a 14 percent decrease in the number of Primary Care Health Manpower shortage areas between December 31, 1983 and September 30, 1984 along with a 24 percent decrease in the number of primary care physicians needed in these areas. Nevertheless, we still predict that there will be a number of geographic areas and population groups which will not reap the full benefit of the increasing supply and diffusion. Hence, there will still be a need for the NHSC to address those areas which will not be served through the private sector. The NHSC foresees a minimal future field strength made up of a mix of obligated and unobligated health professionals, who will be available to supply needed health manpower to those medically underserved "poor populations."

The NHSC is a program which addresses one aspect of the health care needs of the poor, complementing and not competing with the private sector. With continued support at an appropriate, albeit somewhat lower amount, the NHSC will continue to provide health manpower resources to appropriate medically underserved populations.

Whether the NHSC finds itself without a supply of "obligated" physician manpower, or with only a limited supply of scholarship recipient providers, the solution to assuring an adequate supply of physicians for the NHSC to meet the needs of the underserved is through two mechanisms: 1) assisting organized systems of health care to hire manpower, and 2) health care provider retention through career opportunities. Current NHSC program activities address both of these long range strategies, as well as the placement and support of current health care providers in areas of medical underservice.

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Question. How will we educate future physicians who may need this scholarship assistance to get through school?

Answer. The 1986 budget continues Health Professions student loans and HEAL loan programs which will support 51,400 students.

HEALTH PROMOTION/DISEASE PREVENTION

Question. Health promotion and disease prevention are the hope of the future in our efforts to cut health care costs. In some schools of public health, the capitation program helps maintain an adequate faculty and traineeships are the backbone of these schools' assistance to low-income students. Last year our bill provided $11.6 million to help train students in various fields dealing with health promotion and disease prevention. You have requested that all 5 of these programs be eliminated.

Don't you think $11 million is a good investment to help train young people who will lead the way in this field?

Answer. The Public Health Service has a long history of support of education and training of public health and health administration personnel with appropriations under the PHS Act beginning in 1956. Funds were used to support schools of public health and free-standing programs in epidemiology, biostatistics, health administration, and other specialties. State and local health departments were assisted in short-term training courses and continuing education. A variety of fellowships and traineeships were provided.

During that time, the educational establishment in public health, preventive medicine, and health administration grew significantly. Schools of public health increased from 12 to 23. There are now about 250 other programs available in these specialties, for many of which the supply of personnel is not a cause of major concern, although a few specialties continue to be in demand.

HEALTH PROFESSIONS ANALYTICAL STUDIES AND REPORTS

Question. Your agency has described the Health Professions Analytical Studies and Reports program which provides "up-to-date, carefully analyzed information on the supply, distribution and utilization of practicing health professionals and on health professions students and institutions," -- information used by Congress, the Department and the private sector in making national health policy decisions.

Last year we appropriated $2 million for this program. For fiscal year 1986, you are requesting that it be eliminated.

The Public Health Service Act directs the Secretary to carry out a wide variety of data collection and analytical activities through this program.

How do you propose to collect data on all aspects of health care -- as the Department is intended to do -- without any money?

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Answer. Information on shortage areas are relatively current and up to date. On other aspects of health care, we will rely on the most recent information in order to make health policy decisions. Where these activities are helpful in making decisions considered priorities of the Federal government, it will be possible to support these activities with resources available elsewhere in the Department.

Question. Who will have responsibility for designating health care shortage areas?

Answer. Other Department programs will assume this responsibility.

HEALTH PROFESSIONS TRAINING

Question. It is estimated that America's population of 75 and older will increase over 50 percent by the year 2000. Recognizing this, Congress appropriated $5 million for geriatric training.

You are proposing to eliminate the funding in FY 1986.

Do you feel we have an oversupply of geriatric specialists, thus making this training unnecessary?

Answer. There is no precise point at which an adult becomes a "geriatric patient," and most of the diseases and health care problems of the elderly are not unique to any age group. Consequently, we believe that competence in health care for the aged should be fostered in the total health care system, and that specialists in geriatrics are needed in research, in the conduct of health professions training, and in analyzing and solving the particular problems of providing care to this group. Thus, intent of the establishment of Geriatric Education Centers has been to integrate geriatric training wherever appropriate into all aspects of health professions education, including allied health personnel providing rehabilitation or with other direct patient care responsibilities of nurses, physicians, dentists, podiatrists,and other practitioners.

A task of this magnitude must be the responsibility of the health professions education system as a whole, with the Government showing leadership and encouraging actions by the schools, professional associations, and accrediting authorities. A trend toward increased emphasis on geriatrics-related training is currently in evidence. It does not appear that the absence of our support will halt this trend.

Question. Were the needs of the elderly for geriatric specialists considered when your funding was recommended for health professions training?

Answer. A variety of highly competitive needs were reviewed in the preparation of the PHS budget for fiscal year 1986. In the face of severe constraints on discretionary spending, health professions training was viewed as a responsibility of the States, to the extent that it cannot be self-supporting. The obvious desirability of training practitioners and health workers to better serve the elderly was not overlooked, and we believe that States medical schools and the private sector will respond.

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Questions Submitted by Senator Ted Stevens

FEDERAL EMPLOYEE OCCUPATIONAL HEALTH

Question. Please provide the Committee with the following information relating to the proposed termination of funding for the Federal Employee Occupational Health (FEOH) program:

What is the total value of services currently provided by FEOH?

Answer. In FY 1985, FEOH anticipates providing approximately $16,345,000 of occupational health standards setting, consultation and delivery services to Federal agencies. Over $15,700,000 of this amount consists of "reimbursable" services provided to over 2,500 different Federal agency headquarters and field units at over 160 locations.

Question. What savings to the Federal government will be realized by the contracting out on an agency-by-agency basis of the current services provided by FEOH and health units?

Answer. In the short run, none that we are aware of. However, there will be a reduction of approximately 231 in the number of Federal employees delivering such services. A reduction in outyear cost due to reduced Federal pension benefit expenses can be anticipated.

Question. What incentives will exist for Federal agencies to implement employee occupational health programs in lieu of the current FEOH program?

Answer. The FEOH program is not being eliminated. The FEOH will no longer directly provide occupational health services on a reimbursable basis but individual agencies will be able, at their discretion, to continue such services by alternative means. The FeOH will continue to provide reimbursable occupational health standards setting, consultation and technical advice to Federal management. Such services will be directed to encourage and assist such managers to provide comprehensive state-of-the-art occupational health/worksite health promotion service in order to increase Federal productivity and reduce absenteeism, lost time and financial liability. Eighty-five Federal positions -- primarily for occupational health profession will be retained for this purpose. These professionals will assist Federal managers to develop alternative strategies for securing the actual delivery of occupational health services.

Question. What are the estimated health care cost savings resulting from the current FEOH program, and what increased health care cost savings might be expected under the proposed new system?

Answer. There is no specific comprehensive data available from the Federal sector estimating the health care cost savings. Currently, in cooperation with the Office of Personnel Management and the General Services Administration, FEOH is attempting, as a first step, to determine the scope and intensity of occupational health/worksite health promotion activities within the Federal sector. To the extent that such activities exist, we would

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anticipate that they would result in cost savings equivalent to those realized in the private sector for similar activities. Cost savings of 50 percent and higher in health insurance expenditures, accident rates, workmen's compensation, absenteeism, etc. are documented by various studies in the literature. Given the heavy emphasis of FEOH on health promotion activities -- 3,926 programs in FY 1984 --, it is anticipated that similar savings are realized by FEOH programs, to the extent that Federal managers continue to provide such occupational health services with consultation from FEOH, such savings would be expected to continue. At present, FEOH is in the process of publishing new essentials, and standards for comprehensive state-of-the-art occupational health programs. If such standards are embraced by Federal managers, even further cost savings would be anticipated.

COMMUNITY HEALTH CENTERS

Question. Given the Administration's proposed reductions in Medicare and Medicaid spending -- which will no doubt increase the pressure on publicly-supported community health clinics -- how do you justify a proposed $15 million reduction in Community Health Center (CHC) funding, and a $10 million cut in National Health Service Corps (NHSC) support for fiscal year 1986?

Answer. The apparent $15 million reduction in CHC funding is due to the fact that the 1986 proposal does not reflect the $15 million reprogrammed from the NHSC to CHC program during FY 1985. The $10 million reduction in the NHSC support for FY 1986 reflects the continuing reductions in the NHSC Federally employed field staff from 650 in FY 1985 to 570 in FY 1986.

Question. These programs serve the poor -- often the poorest of the poor.

Aren't they part of the "social safety net"?

Answer. These programs are primarily State responsibilities, hence our proposal to transfer operational responsibility for the Primary Care Block Grant to States.

Question. In recent years, the Congress provided limited increases for Community and Migrant Health Centers. Moreover, we have included report language directing the Department to assure that current service levels at existing centers are maintained before new activities are initiated.

What steps have you taken to assure this directive is carried out?

Answer. The Bureau of Health Care Delivery and Assistance (BHCDA) of HRSA annually reviews each of the approximately 600 continuation grant applications submitted by CHCs to assure that adequate funds are provided to maintain existing health services while critically reviewing each health center's base grant level to assure that funds are spent only in the most efficient and effective manner possible. BHCDA conducts such reviews based on a standard series of funding criteria including such issues as individual health center performance on financial and administrative indicators as well as a continual review of the relative need of the

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population served by the health center. These individual health center reviews have been and, we expect, will be the most appropriate mechanism to assure that health centers receive appropriate funding levels, while allowing BHCDA the management capability to utilize funds in the most prudent and cost effective manner. This process, which has been used for over 10 years, results in projects receiving increased funding level or decreased funding based solely on their need and performance.

HEALTH PROFESSIONS EDUCATION

Question. The Administration has proposed an abrupt termination of health professions education funds.

What effect will this have on Federal support for financially distressed minority schools -- Meharry Medical, Meharry Dental, Tuskegee, and Xavier?

Answer. The four schools are currently in their fourth year of assistance through the Advanced Financial Distress program and previously received assistance under the Financial Distress program from FY 1973 to FY 1981. They have made substantial progress toward attaining the goals specified in their financial plans -- revamping accounting systems, initiating financial planning systems, attracting new senior staff, increasing tuition charges,and expanding private fund raising.

NATIONAL HEALTH SERVICE CORPS

Question. The Conference Report on the FY 1985 appropriation included language which would permit you to reprogram up to $15 million from the NHSC account to Community Health Centers to support scholarship obligors newly assigned under the Private Placement Alternative (PPA).

What is the status of this reprogramming?

Answer. The reprogramming of $15 million from the NHSC account to CHCs has been accomplished.

Question. How many PPA assignees will this $15 million support?

Answer. In view of the number of CHCs involved and the differing needs among the CHCs, we are now reassessing each PPA opportunity. A precise answer to this question cannot be provided until this reassessment is completed later in April.

Question. How many obligors do you plan to place in PPA assignments in this fiscal year?

Answer. Our current projections indicate that we will place approximately 700 new PPA assignees in CHCs in this fiscal year. An additional 140 obligors will be placed in positions being vacated by obligors who have completed their obligation; funds for these positions have already been made available.

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Question. In view of the number of obligors you are planning to assign to the PPA in this fiscal year, will any additional reprogramming be necessary?

Answer. We are not requesting any additional reprogramming of FY 1985 funds from NHSC to CHCs at this time.

Question. If additional reprogramming is required, what would be the impact on your FY 1986 budget if a reprogramming request were denied?

Answer. We do not have any plans for a reprogramming at this time.

Question. Does the FY 1986 request for the Primary Care Block Grant contain sufficient funds to continue the support of PPA assignees whose first year of support is being funded with the money reprogrammed in FY 1985?

Answer. The current request for the Primary Care Block Grant for 1986 does not reflect any FY 1985 reprogramming actions. The request assumes passage of the expanded Primary Care Block Grant proposal and assumes that States will operate the program in FY 1986.

Question. How do you propose to support these assignees? What are the options that you have and that we in the Congress have to ensure that these assignees are supported in FY 1986?

Answer. The budget proposal assumes that the States will be responsive to the issues involved in operating their programs in FY 1986.

Question. Will you have a problem supporting the new PPA obligors to be assigned in FY 1986 — i.e., are additional resources needed in order to make these assignments?

Answer. The budget request assumes that the States will ensure that there are sufficient resources to make these assignments.

Question. What alternatives exist with respect to providing the necessary funding support for these individuals?

Answer. Since the States will be responsible for administering these centers, we cannot speculate on their alternatives.

Questions Submitted by Senator Mark Andrews

FAMILY PRACTICE

Question. As you may recall, last year during your appearance before this subcommittee, we discussed at length the possibility of organizing projects similar to that of the North Dakota CARES project (Coordinated Ambulatory Rehabilitation Evaluation Service) in other medically underserved rural areas. Are we any closer this year in organizing another CARES project in another medically underserved rural area?

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Answer. Yes, we are closer to organizing other projects which are similar to CARES. The primary mission of the CARES project is to build the capacity of local providers around a service focus. The project is concerned with improving the quality of care provided, maximizing third party reimbursement, and demonstrating sound fiscal and management capacities.

During FY 1984 and continuing into FY 1985, a major emphasis of BHCDA has been upon developing rural consortia which resemble the CARES concept in many ways.

Where individual health centers, for a variety of reasons, are not effective in the delivery of health services, BHCDA will consider a variety of management tools to assist the centers. Consortia development, mergers, consolidations are examples of such management tools. The purpose of the emphasis upon consortia is to support the overall strengthening and growth of viable systems of care in rural areas. The small population base and relative remoteness of most rural areas has resulted in the development of small, frequently isolated CHC/MH, freestanding NHSC sites, private health care practices and hospitals. Many of these providers lack the financial, staffing and technical resources required to develop coordinated multi-specialty delivery systems that provide stable and continuing support for rural practitioners and users. Through consortia such sites link together clinically and/or administratively to provide coordinated comprehensive services which none could singly support.

Question. You also indicated in your testimony before this subcommittee that you have learned a great deal from the CARES project. Could you share with us the benefits that are derived from this project?

Answer. The benefits derived from the CARES program involve not only these directly to the citizens of North Dakota, but also in providing a test for several elements of the rural consortia program which was described earlier. The purpose of consortia is to support the overall strengthening and growth of viable systems of care in rural areas. This is accomplished linking sites together clinically and/or administratively to provide coordinated comprehensive services which none could singly support.

Question. Last year, the CARES project received an allocation of $200,000 for 1985. In terms of dollars, what do you envision for the CARES project in 1986?

Answer. We cannot say yet what the level of funding for the CARES project in 1986 will be. As the project has consistently tried to deliver services and training while holding costs level through increased efficiency, we would expect that their resource allocation request would remain at or around the $200,000 level provided in 1985.

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Questions Submitted by Senator Quentin N. Burdick

HEALTH PROFESSIONALS

Question. Dr. Graham, I was very disappointed to see the deep cuts proposed in your budget, which I think is one of the most important within HHS for the rural areas of our country. I was especially disappointed to see the total elimination of funding for the health professions, including nursing and family practice training. I think these cuts are a mistake, and I do not plan to support them. Nursing, to take just one example, is changing dramatically. Numbers alone do not tell the whole story. Nurse practitioners are doing more and more; gerontological nursing is growing in importance, and advanced nurse training is a continuing need that we cannot and should not simply cut off.

I noticed that one of the HHS budget documents states that one reason for these cuts in health professions training is the "improving distribution of health professions training is the "improving distribution of health professionals." The evidence in my own State of North Dakota is that there are some more health professionals in the medium sized rural communities, but there are still many, many areas, especially in the more remote areas, where there are virtually no health professionals.

What do you think the outlook will be for adequate health care in those remote rural areas in the future, given the cuts you have proposed?

Answer. It is somewhat difficult to document the extent to which different communities have benefitted from the expanded supply of health professionals because recent data do not exist for most occupations at that level of geographic detail. In the case of physicians there has been substantial gain in the number practicing in non-metropolitan areas, but the size of this gain varies greatly by type of areas and by type of physician. A recent study of the practice locations selected by young physicians showed that all types of counties are gaining such individuals, but that each and every county does not necessarily gain. About 92 percent of the counties between 25,000 and 50,000 population gained at least one young physician, and 31 percent of the counties with less than 10,000 population did so.

NATIONAL HEALTH SERVICE CORPS

Question. Concerning the National Health Service Corps (NHSC), your justification indicates that the physicians serving the NHSC sites are a chief reason why the number of health shortage areas had declined. You further state that no scholarship money has been recommended for fiscal 1986 because scholars now in the pipeline will provide adequate staffing for the rest of this decade.

First of all, I must question this assumption, since the NHSC, despite its success, has not solved the manpower shortage problem.

Second, however, and more disturbing, is your short-sighted outlook. The end of the decade is only 5 years away. Why won't NHSC personnel be needed after that time? Will we not have any shortage areas any more?

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Answer. While recent analyses indicate that the number of geographic HMSAs in the United States is gradually but certainly decreasing, this does not imply that all the health care needs of the medically underserved are being met by the presently available manpower. This fact does form the basis by which the NHSC has already provided health professionals to specific population groups and institutions which are unable to recruit or retain adequate health manpower to serve their health care needs. The NHSC expects this trend away from geographic HMSAs and towards population and facility HMSA designations to continue.

FAMILY PRACTICE

Question. I am also very concerned about your cut of the Family Practice training program and Family Practice departments. Because family practice emphasizes preventive and ambulatory care, these training programs are uniquely dependent on funding sources other than patient care revenues and are particularly vulnerable as those other sources dry up. In addition to the elimination of the Public Health Service grants, the Administration has also proposed freezing the Medicare payment for direct costs of medical education and reducing by 50 percent the indirect medical education adjustment. As such resources in teaching hospitals become more scarce, the elimination of family practice training programs becomes more likely because hospitals will have fewer and fewer incentives to retain programs like these, which frankly, are not big money-makers. The problem is, the fact that they are not big money-makers is exactly why we should encourage them.

My question is, in light of all this, if the training grants are eliminated, what alternative sources of funding do you realistically see available for support of family practice training programs?

Answer. Other principal sources of support may be State and local governments. Through ongoing technical assistance to applicants and grantees, Federal staff continuously emphasize the need for primary care programs to become institutionalized. Similarly, this concept is emphasized at pertinent professional meetings and in the review process when competitive proposals are being evaluated. Between 1973-1984 — according to AMA residency directories — the number of family practice programs and filled residency positions grew from 206 - 386 and 1,765 to 7,408 respectively. Up to now, sources of support have been multiple, and tend to vary from program to program.

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OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

STATEMENT OF JAMES O. MASON, M.D., ACTING ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

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DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator WEICKER. Next we will hear from Dr. James O. Mason, the Acting Assistant Secretary for Health.

Dr. Mason, if you would give us a brief summary of your statement. The statement in its entirety will be included in the record. Please proceed.

[The statement follows:]

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STATEMENT OF JAMES O. MASON

I appreciate the opportunity to appear here today to discuss the budget request for the two appropriations in the Office of the Assistant Secretary for Health (OASH)--the Public Health Service Management (PHS) appropriation request of $105.2 million and the Retirement Pay and Medical Benefits for Commissioned Officers appropriation request of $97.1 million.

PUBLIC HEALTH SERVICE MANAGEMENT

The budget request for the PHS Management Appropriation includes funding for a number of high priority programs which operate under the direct supervision of the Assistant Secretary for Health. These programs account for $87 million or 83 percent of the funding requested in this account. The remaining funds support the overall management and direction activities for PHS.

The Fiscal Year 1986 appropriation request will provide a funding level consistent with 1985 for all program activities in this account and will permit expansion in selected areas. As part of a Government-wide effort to reduce administrative and management activities, a reduction of $2.9 million and 53 staff years is reflected in the various budget activities in this appropriation.

The request before you includes a total of $48 million for the National Center for Health Statistics (NCHS), an increase of $5.4 million over 1985. The data gathering and analysis activities of NCHS provide an invaluable resource for PHS, other agencies of the Federal government and the general public. The data collected by NCHS cover a broad range of topics including statistics on vital health events, individual health status, costs and use of health care and availability of health facilities.

The increased funding requested in 1986 will permit NCHS to do the planning and developmental work for the National Health and Nutrition Examination Survey (NHANES) to be conducted in 1988. The data collection for the most recent National HANES was completed in 1980. The plannned survey will be a comprehensive review of individual health status and the data will be obtained from physical examinations of a selected sample of approximately 60,000 people over 6 years. The money requested in FY 1986 will be used to develop a comprehensive survey design, to purchase diagnostic equipment, to purchase and renovate mobile examination centers, and to develop survey methods and standards.

Additional funding is requested to enable NCHS to acquire linked birth and infant death records from all States in order to conduct an intensive investigation of the correlates of risk of infant death. The amount requested also includes funding for the next cycle of the National Survey of Family Growth which provides national statistics on fertility, family planning and reproductive health of American women in the childbearing years.

This appropriation request also funds the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA). NCHSR/HCTA supports an extramural research program of investigator initiated proposals which undergo peer review. These studies make a significant contribution to the expansion of

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the knowledge base for health policy analyses. Projects focus on the development of methodologies required for future evaluation of alternative mechanisms for organizing, financing and delivering health care, including the creation and validation of methods for determining cost benefit and cost effectiveness. Extramural program research findings have expanded the knowledge base and have highlighted areas where the potential exists for providing health services more efficiently, effectively and at lower cost. For example, research supported by the Center resulted in the development of a system of classifying patients treated in intensive care units by means of physiological values and chronic health status. The APACHE (Acute Physiology and Chronic Health Evaluation) system is being used to determine assignment of patients to critical care units, based on the severity of their symptoms and the prognosis. Another research grant supported by the Center culminated in the development of a procedure which eliminates the need for unnecessary x-ray of injured limbs. It is estimated that this procedure could save as much as $139 million in x-ray costs without compromising the quality of care. Special program attention for 1986 will continue to develop projects in health care technology assessment, health promotion and disease prevention in the primary care setting, the role of market forces in utilization of care and attempts to develop resource allocation and program evaluation support for units of State and local government. This request will permit 12 new projects to be funded in 1986 with continuation of 46 current projects. The Center's intramural program contains two information sets, the Hospital Studies Program and the National Medical Expenditures Survey (NMES), aimed at understanding the financial aspects of hospital operations and for documenting health care expenditure patterns of the American public. Both of these projects are frequently called upon for special analyses by CBO, Congressional Committees, OMB, the insurance industry and units of State and local government. The request includes $3.5 million in 1986 for planning and development and pretesting for the NMES field survey which is scheduled for January of 1987. This is essential if data is to be available in 1988 with respect to the dramatic changes which are presently occurring in how Americans finance their health care. It is a cooperative venture with HCFA and NCHS.

The National Center's User Liaison Program is continuing to strengthen its working relationship with State and local government and building new relationships with many of the new business health coalitions in various parts of the country. Last year, the Center's User Liaison Program sponsored fifteen workshops and seminars for officials from thirty states on a variety of current health care delivery and financing issues. The Program also sponsored a workshop in health care cost containment for the Greater Portland Oregon Business Group on Health and a seminar for a group of business coalition leaders the purpose of which was to identify a topic for a synthesis of health services research which would be useful to business coalition leaders. In 1985 the Center intends to expand its business coalition activity, with a particular focus on Wenberg's small area variation in the use of medical services. The Center's request of $16.2 million is approximately the same as the 1985 level.

Another high-priority program funded in this account is the Adolescent Family Life Program. The objective of the AFL program

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is the development of effective alternative approaches to the multi-faceted problems of adolescent pregnancy.

The program supports demonstration projects that provide communities around the country with model programs for effective care services for pregnant adolescents and adolescent parents and prevention services to encourage postponement of adolescent premarital sexual activity. Care demonstration projects are showing success in reducing medical complications and repeat pregnancies. They show increasing school completion, job placement, parenting skills, adoption consideration and positive parent and male participation. Prevention projects are reaching out to families to facilitate parent-child communications and finding that families are responsive and benefiting from improved communication. Existing research verifies that parents play an important role in prevention, and new research is moving us toward understanding the circumstances in which they could play an even greater role. The results of the research projects and the strengthening of the preliminary results with additional evaluation of service delivery models will supply much-needed information for service providers and policymakers. The 1986 budget request of $14.7 million will continue the 1985 level of support and will fund a total of 90 projects.

The 1986 budget request for this account will provide continuing support for the three programs which focus on preventing disease and promoting good health practices. These programs--Smoking and Health, Physical Fitness, and Disease Prevention and Health Promotion--educate the public about occupational, societal, environmental and behavioral factors which affect health. Efforts are focused on encouraging beneficial lifestyle changes through a variety of activities including media campaigns, clearinghouses and workshops. In addition to coordinating activities within PHS and the Department, these programs foster cooperative working relationships with State and local governments, voluntary health organizations and public and private groups. These cooperative working relationships enable the Federal government to communicate with the general public. In FY 1986, in addition to the ongoing program activities, the Office on Smoking and Health will disseminate the results of the passive smoking study being initiated in 1985. The Office of Disease Prevention and Health Promotion will undertake a major public education effort as part of the Healthy Older People Program, will initiate dissemination of the findings and recommendations of the first Surgeon General's Report on Nutrition and Health being developed in 1985, and will complete the process of refining our prevention objectives for the year 1990. In addition, the results of the Youth Physical Fitness Survey will be published by the Physical Fitness and Sports Activity. Our funding request for these three programs will provide levels of support approximately equal to those in 1985.

We are requesting $17.9 million and 300 staff years for the management and direction of the Public Health Service which is a reduction of $1.8 million and 39 staff years from the 1985 level. This reduction reflects the Administration's commitment to reduce the cost of administrative and management activities.

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RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

The Retirement Pay and Medical Benefits for Commissioned Officers appropriation funds retirement payments to Public Health Service Commissioned Officers, payments to survivors of officers who elected to receive a reduced annuity, and the costs of medical care of active duty and retired officers, their dependents and survivors.

The fiscal year 1986 request of $97.1 million assumes the enactment of a legislative proposal that would postpone the cost-of-living increase scheduled in January 1986 to January of 1987 for a savings of $2.6 million. This is in accordance with a government-wide effort to contain cost-of-living adjustments for various Federal retirement plans.

The Administration is also proposing to change this account from an indefinite to a definite appropriation. As a result, the amount requested in 1986 includes a $16.2 million reserve fund which will be available only to the extent necessary to pay costs and benefits not anticipated in the budget estimate.

I will be happy to answer any questions you may have.

BIOGRAPHY OF JAMES O. MASON

POSITION : Director, Centers for Disease Control

BIRTHPLACE AND DATE : Salt Lake City, Utah, June 19, 1930

EDUCATION

B.A. - 1954, University of Utah, Salt Lake City, Utah
M.D. - 1958, University of Utah, Salt Lake City, Utah
M.P.H. - 1963, Harvard School of Public Health, Boston, Massachusetts
Dr.P.H.- 1967, Harvard School of Public Health, Boston, Massachusetts
Internship, 1958-1959, Johns Hopkins Hospital, Baltimore, Md.
Residency, Internal Medicine, 1961-1962, Peter Bent Brigham Hospital, Harvard Medical Service, Boston, Massachusetts

EXPERIENCE :

2/85	: Acting Assistant Secretary for Health
1983-1985	: Director, Centers for Disease Control
1979-1983	: Executive Director, Utah Department of Health
1978-1979	: Associate Professor and Chairman, Division of Community Medicine, Department of Family and Community Medicine, University of Utah College of Medicine
1976-1978	: Deputy Director of Health, Utah Division of Health
1970-1976	: Commissioner, Health Services Corporation, The Church of Jesus Christ of Latter-day Saints
1969-1970	: Deputy Director, Centers for Disease Control (CDC), DHEW, Atlanta, Georgia

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1968-1969 : Chief, Infectious Diseases, Latter-day Saints Hospital and Assistant Professor, Department of Medicine and Preventive Medicine, University of Utah, College of Medicine

1964-1968 : Deputy Director, Bureau of Laboratories, Centers for Disease Control (CDC) DHEW, Atlanta, Georgia

1961 : Chief, Surveillance Section, Epidemiology Branch, Center for Disease Control (CDC), DHEW, Atlanta, Georgia,

1960 : Chief, Hepatitis Surveillance Unit, Epidemiology Branch, CDC, Atlanta, Georgia

1959 : Chief, Epidemic Intelligence Service, CDC, Atlanta, Georgia

TEACHING APPOINTMENTS : Clinical Professor, Department of Family and Community Medicine, University of Utah College of Medicine, May 1, 1979 to December 1983

Clinical Professor, Department of Pathology, University of Utah College of Medicine, May, 1980 to December, 1983

ASSOCIATION MEMBERSHIP : Chairman, Utah Governor's Advisory Committee for Comprehensive Health Planning, 1975 to 1977

Chairman, Joint Residency Committee in Preventive Medicine and Public Health University of Utah College of Medicine, 1975 to 1980 Member, Utah Cancer Registry Research Advisory Committee, 1976 to 1983

Chairman of Board, Hospital Cooperative of Utah, July, 1977 to 1979 Chairman, Utah Health Planning and Resource Development Advisory Group Executive Committee 1977 to 1979

Member, twenty-two other committees or organizations

HONORS : Alpha Epsilon Delta, University of Utah 1954

Phi Kappa Phi, University of Utah, 1956

Alpha Omega Alpha, University of Utah, 1957

Roche Award, University of Utah, 1957

Wintrobe Award, University of Utah, 1958

Delta Omega, Harvard University, 1963

Distinguished Alumni Award, University of Utah, 1973

Beatty Award, Utah Public Health Association 1979

Administrator of the Year Award, Brigham Young University, 1980

Sigma XI, CDC. Atlanta, 1964

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INTRODUCTION OF ASSOCIATES

Dr. MASON. Mr. Chairman, I am James Mason. You have already given my title. I am accompanied here by Mr. Peter Bersano, Acting Assistant Secretary for Health Operations. He is also the Acting Director of our Office of Management within the Office of the Assistant Secretary for Health.

I also have with me other members of our staff who will assist me in answering questions that you might have.

OASH BUDGET REQUEST

I appreciate the opportunity to appear here today to discuss the budget request for the two appropriations in the Office of the Assistant Secretary for Health: the Public Health Service management appropriation request of $105.2 million and the retirement pay and medical benefits for commissioned officers appropriation request of $97.1 million.

The budget request for the PHS management appropriation includes funding for a number of high priority programs which operate under the direct supervision of the Assistant Secretary for Health. These programs account for $87 million or 83 percent of the funding requested in this account. The remaining funds support the overall management and direction activities for PHS.

The request before you includes a total of $48 million for the National Center for Health Statistics, an increase of $5.4 million over 1985. The increased funding requested in 1986 will permit NCHS to do the planning and development work for the national health and nutrition examination survey.

This appropriation request also funds the National Center for Health Services Research and Health Care Technology Assessment. The 1986 request of $16.2 million is approximately the same as the 1985 level and will support the ongoing intramural and extramural research activities as well as the information dissemination activities of the User Liaison Program.

The amount of $14.7 million is requested for the Adolescent Family Life Program. This program supports demonstration projects that provide communities around the country with model programs for effective care and prevention services for pregnant adolescents and adolescent parents.

Continuing support is requested for the three programs which focus on preventing disease and promoting good health practices. These programs—smoking and health, physical fitness, and disease prevention and health promotion—educate the public about occupational, societal, and environmental and behavioral factors which affect health.

Our funding request for these three programs will provide levels of support approximately equal to those in 1985.

We are requesting $17.9 million and 300 staff years for the management and direction of the Public Health Service, which is a reduction of $1.8 million and 39 staff years from the 1985 level. This reduction reflects the administration's commitment to reduce the cost of administrative and management activities.

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The fiscal year 1986 request for the retirement pay and medical benefits for commissioned officers appropriation of $97.1 million will fund all entitlement payments in this account.

This request assumes the enactment of a legislative proposal that would postpone the cost-of-living increase scheduled in January 1986 to January 1987 for a savings of $2.6 million. This is in accordance with the Governmentwide effort to contain cost-of-living adjustments for various Federal retirement plans.

The administration is also proposing to change this account from an indefinite to a definite appropriation. As a result, the amount requested in 1986 includes a $16.2 million reserve fund which will be available only to the extent necessary to pay costs and benefits not anticipated in the budget estimate.

I will be happy to answer any questions you may have.

Senator WEICKER. Thank you very much, Dr. Mason.

BUDGET REQUEST TO DHHS AND OMB

Senator WEICKER. The President's budget request for the Office of the Assistant Secretary for Health totals $105,155,000. What was the amount requested by you or your predecessor, Dr. Brandt, to the Secretary?

Dr. MASON. The amount requested was $167.7 million.

Senator WEICKER. Can you tell us which accounts, if any, received reductions in negotiations with the Department or with OMB?

Dr. MASON. In answering that, in the PHS management appropriation, there was a total reduction of $62.6 million; $11.6 million of that was in the National Center for Health Services Research and Health Care Technology Assessment. This amount would have funded 38 additional new research grants.

There was a reduction of $22.4 million in the National Center for Health Statistics. Automation projects to automate surveys, vital statistics data collection and transmission, additional funding for national health and nutrition examination surveys, and other money related to the Haines survey were reduced.

There was a reduction of $3.9 million in adolescent family life and a $2.3 million reduction in PHS management. There were also reductions in PHS termination expenses, national youth sports, smoking and health, disease prevention and health promotion.

PREVENTION OBJECTIVES

Senator WEICKER. Your statement indicates that your office will be refining your prevention objectives for the year 1990. The original announcement mentioned specific measurable objectives in 15 disease and prevention priority areas.

Does your refinement of these objectives mean the Public Health Service is lowering its sights?

Dr. MASON. No; that is not the case, and I would like to call on Dr. Michael McGinnis, Deputy Assistant Secretary for Health, who is di-

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rectly responsible for that activity, to report on the changes that are being made.

Dr. McGINNIS. Mr. Chairman, thank you.

The midcourse review, which is the name for the exercise we are currently engaged in, is an effort designed to look at where we are across the board in obtaining those objectives in the 15 areas and to identify activities or efforts in a couple of respects.

One, where is the objective misstated? That is, is there a better way to phrase the objective so that we can be more specifically addressed to the target? Two, where ought we to change our program activities? Is there some way in which our programs need to be redirected in order to improve the prospects for obtaining the objective? Three, we are looking at what kinds of objectives we ought to begin considering for the year 2000.

So the answer is, as Dr. Mason stated, we are not changing the objectives. No numerical change will be made in any objective. We are, rather, undertaking a comprehensive assessment of what we have to do to enhance our efforts in obtaining the objectives.

Senator WEICKER. Has the Department's request for a decrease in NIH activities affected these objectives for 1990?

Dr. MASON. No, sir; the main change in the NIH appropriation was in the number of research grants that would be funded in fiscal year 1985 and in the future, and although one really can't tell because basic research done in 1985 may have applicability 10, 20, 30 years from now, but there won't be that effect.

Senator WEICKER. Thank you very much, doctor. That is the point I have been trying to get through to the Secretary for a couple of years.

How much is NIH spending on disease prevention research?

Dr. MASON. For the National Institutes of Health, in the President's 1986 budget, there is $1.144 billion for prevention research.

MEDICAL TECHNOLOGIES AND PROCEDURES

Senator WEICKER. A number of agencies have responsibility for research regarding the safety and effectiveness of medical technology and procedures, in addition to the Center for Health Services Research. Specifically NIH supports a number of clinical trials, mainly to assess new technologies and procedures. HCFA and PROPAC also play a role in this area.

What kind of coordination or interaction occurs between these agencies? What role do you see NIH playing in support of the Center's mission of assessing new and existing technology and procedures?

Dr. MASON. I am afraid that it would be more appropriate for me to submit something in writing to you on that, Mr. Chairman.

Senator WEICKER. All right.

[The information follows:]

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COORDINATION OF TECHNOLOGY ASSESSMENT ACTIVITIES

The National Center for Health Services Research and Health Care Technology Assessment serves as the lead PHS organization in preparing recommendations to HCFA with respect to reimbursement coverage issues. At HCFA's request, the Center will perform assessments of the scientific and clinical issues germane to determining if a given technology is usual and necessary. NCHSR does not collect original data or conduct primary studies, but rather draws on data available from FDA and NIH in addition to information provided by manufacturers or presented in the literature. NIH and FDA as well as other PHS agencies review, when appropriate, our assessment and findings. There is extensive research activities in the area of technology assessment. Because NIH processes receipt of grant applications for us on a contractual basis, we have an effective mechanism for coordination with them. The PROPAC research agenda is under development and discussions have been held with Dr. Altman, the Chairman, and with Dr. Steinwald, the Deputy Staff Director of PROPAC, to discuss how to enhance the complementarity of our research programs.

We see the role of NIH as continuing to fund clinical trials, which we consider one of the fundamental building blocks of health care technology assessment. In addition, we anticipate that much of the longitudinal data on large cohorts of individuals which has been collected for various NIH investigations could be used by NCHSR to evaluate the effectiveness and cost effectiveness of specific therapeutic interventions.

We also anticipate that the Office of Medical Applications of Research [OMAR] will continue to serve as a liaison between the Center's Office of Health Technology Assessment and the bureaus, institutes, and divisions of NIH, so that the benefit of clinical knowledge at NIH can be brought to bear on the Medicare coverage recommendation process.

HEALTH CARE TECHNOLOGY ASSESSMENT

Senator WEICKER. It is my understanding that the legislation that charged you with the additional responsibility of health care technology research and assessment also provided your office with a source of funds to conduct that research and assessment.

Yet the budget justifications do not mention that source of funding, and your budget request is $249,000 less than in fiscal year 1985.

What is the maximum amount of funding that could be made available for technology assessment under the 1984 amendment?

Dr. MASON. Dr. John Marshall, do you want to respond to that? He is the Director of the National Center for Health Services Research.

Mr. MARSHALL. That would be about $4.8 million, Senator.

Senator WEICKER. Do you want to explain the discrepancy here, Mr. Marshall, or the differences, if you will, as to amount?

Mr. MARSHALL. The statute spoke to making available 7.5 percent of the money that is set aside in the Department for evaluation activities. The question is whether the intent of the Congress in that case was to set aside 7.5 percent of the total amount that might be made available, that is up to 1 percent of the grant and contract appropriation, which would be about $4.8 million, or 7.5 percent of the amount which was planned for obligation, which was $20 million. So the percentage of that would be about $1.5 million.

Mr. BERSANO. Senator, I think you should know that we have not over the years actually provided for evaluation the maximum amount that the law allows the Secretary to provide. The 1 percent, for instance, in 1985 would provide about $64 million for evaluation, but we are cur-

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rently in 1985 planning to spend about $20 million. The $1.5 million that is being transferred to the research center is 7.5 percent of that $20 million.

Senator WEICKER. Do you have a question?

Mr. BONGARD. Can you describe what the purpose of this research is and what the long-range impact of it may be?

Mr. MARSHALL. The technology assessment research?

Mr. BONGARD. Right.

Mr. MARSHALL. We would have used that money to look at a number of issues, including the development of methodologies for looking at cost benefit and cost effectiveness of various technologies, which is something that is included in the reauthorization as a priority activity. We would have been able to support studies that looked in addition at the small area variation question and some studies of effects of prospective payment on the health care delivery system.

We are carrying out some of those kinds of activities within our regular appropriation. Because we are speaking here about an extramural research grant program, it is hard to specify exactly what is funded because it has to go through the peer review system. So we could give you a list of what some of those things might be for the record, but we can't produce it now because we don't know what it is we will have.

Mr. MARSHALL. Thank you.

[The information follows:]

POTENTIAL EXTRAMURAL GRANTS

Avorn, Jerome L., Harvard Medical School: Boston, MA. "Strategies to Reduce Inappropriate Use of Blood Products."

Feldman, Roger D., University of Minnesota: St. Paul, MN. "Employer-Based Health Insurance."

Fletcher, Suzanne W., University of North Carolina: Chapel Hill, NC. "Nurse and Physician Interventions to Improve BSE."

Given, Charles, Michigan State University: East Lansing, MI. "Caregiver Responses to Managing Elderly Patients at Home."

Guttmacher, Sally J., Columbia University: New York, NY. "Prenatal Care for Immigrant Women."

Havighurst, Clark C., Duke University: Durham, NC. "Legal Issues in a Competitive Health Care System."

Holahan, John, The Urban Institute: Washington, DC. "Study of Chain Nursing Home Costs, Casemix and Staffing."

Katz, Sidney, Brown University: Providence, RI. "ADL Change for Elderly at Risk of Institutionalization."

Manning, Willard G., The Rand Corp.: Santa Monica, CA. "Economic Costs of Poor Health Habits."

Newcomer, Robert J., University of California: San Francisco, CA. "Life Care Communities: Health Care Costs and Expenditures."

Payne, Beverly C., University of Michigan: Ann Arbor, MI. "Appropriate and Inappropriate Use of Ancillary Services."

Gardner, Reed M., LDS Hospital: Salt Lake City, UT. "Evaluation of a Computerized Infectious Disease Monitor."

Roberts, Russell D., University of Rochester: Rochester, NY. "Theory and Estimation of Voluntary Whole Blood Supply."

Hallstrom, Alfred P., University of Washington: Seattle, WA. "Improved CPR Instruction Via Telephone—A Randomized Trial."

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Butler, Robert, Mount Sinai School of Medicine; New York, NY, "Policy Conference: Paying Physicians for Geriatric Care."

Johnson, Allan N., Hospital Education and Research Foundation; Minneapolis, MN, "Third Party Reimbursement and Patient Resource Use."

Cox, Cheryl L., University of Illinois; Chicago, IL, "Hospital Employee Health: Fitness, Absenteeism and Accidents."

Freeborn, Donald K., Kaiser Foundation Research Institute; Portland, OR, "Consistently High and Low Elderly Users of Medical Care."

Lion, Joanna, Brandeis University, Waltham, MA, "Ambulatory Care Visits Outside the Private Sector."

Grembowski, David E., University of Washington, Seattle, WA, "Dental Demand and Public Oral Health."

Wortman, Paul M., University of Michigan; Ann Arbor, MI, "Utilization of Research on Cardiovascular Technologies."

Ventura, Marlene R., M.S., Veterans' Administration Medical Center; Buffalo, NY, "Reducing Hospital Costs by Increasing Client Participation."

Ciampi, Antonio, Ontario Cancer Institute; Toronto, Canada, "Methods for Exploratory Analyses of Clinical Data Banks."

Hokasen, James, University of Texas Medical Branch; Galveston, TX, "A Bar Code Based Pharmacy Quality Assurance Program."

Kjerulff, Kristen, University of Maryland, Baltimore, MD, "Process of Incorporating Computers into Nursing Practice."

Palmer, R. Heather, Harvard School of Public Health; Cambridge, MA, "Variations in Ambulatory Care Quality and Service Use."

Pollack, Murray M., Research Foundation of Children's Hospital, Washington, DC, "Severity of Illness in Children: A National Study."

Ponies, Walter J., East Carolina University; Greenville, NC, "Economic and Social Factors in Gastric Bypass Surgery."

Vineberg, Shalom E., Institute for Rehabilitation and Research; Houston, TX, "Patterns of Treatment in Long Term Hospitalization."

PROSPECTIVE PAYMENT SYSTEM

Senator WEICKER. What are you doing to evaluate the efforts of the new Medicare DRG-based prospective payment system?

Mr. MARSHALL. We have two or three projects that are presently pending on the extramural side. Much of that work, though, is being done on the intramural side.

The Department has made a major commitment of funds to the hospital cost and utilization program which is a very large data base of hospital discharges. We are updating that data base and we are working very closely with the Health Care Financing Administration. Essentially that data base will provide a good bit of the information that will be needed for the various reports to the Congress over the next 2 years.

In addition, we have a very specific and highly focused study we are doing with the National Cancer Institute that looks at the cost of treating cancer patients who are on protocols in community cancer treatment centers as compared to those who are either in those same kinds of hospitals and not on protocols or not in hospitals who are in that type of organized program. That bears very importantly on the question on the impact of prospective payment on clinical research.

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LONG-TERM CARE

Senator WEICKER. Along one of the lines of questioning with Dr. Graham was this problem of the elderly. As America grows older, the problem of providing and paying for long-term care for the frail elderly will become more acute. Do you have any plans to study the long-term care problem?

Mr. MARSHALL. The Center has for better than a dozen years now had that as a major emphasis. We have funded a lot of projects and continue to fund projects in those areas.

One of the ones that I think is most germane to that is that we have been responsible over the years for funding work that looks at ways of scaling the activities of daily living. That leads to more appropriate placement then of people in nursing home settings with respect to the level of intensity of care that they can use and it gives doctors and other staff people in nursing homes some tools for looking at when they can move a patient within the home from one level of intensity of care to another. That has a lot of important implications for socialization of patients.

Second, we have supported a number of projects which contribute their data into a data bank that is maintained at Brown University by Dr. Sidney Katz. That is a resource for other people doing work in the long-term care area.

We are hoping this year to do more studies looking at the issue of incontinence because when you look at the reasons why people are in nursing homes, a large number of them are there even though the family would like to take care of them, but they can't because of the incontinence problem.

There is some indication from the biological research that more of those are treatable than we had thought. Those are the main areas we have been working in in that direction.

HEALTH STATISTICS

Senator WEICKER. Your budget request reflects an increase of $5.4 million and a decrease of 14 full-time equivalents for the National Center for Health Statistics.

What significant health surveys will the National Center for Health Statistics be conducting or supporting during fiscal year 1986? What survey plans have been postponed because of budgetary limitations imposed upon the Center by the Department or OMB?

Dr. MASON. I would like to ask Dr. Manning Feinleib, Director of the National Center for Health Statistics, to address that.

Dr. FEINLEIB. We are planning to institute the next cycle of the national health and nutrition examination survey. We will be in the field with the national health interview survey. We are also trying to get started on the national medical expenditure survey, in association with the National Center for Health Services Research and Health Care Technology Assessment. This survey will provide definitive information on the expenditures for health care.

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The surveys being postponed are, essentially, our plans to expand the national ambulatory medical care survey. We are hoping to get coverage of ambulatory care outside of office-based practices.

Senator WECKER. What cutbacks, if any, have been made in the frequency and scope of NCHS national surveys over the last 2 years because of funding reductions?

Dr. FEINLEIB. Several of the surveys have been affected by the change in periodicity. We had been hoping to implement the national health and nutrition examination survey. We were getting started here in 1985 to plan for it and get it out in 1987. We have postponed that to be implemented in 1988.

The national survey of family growth was delayed also. There are other surveys, but I think those are the main ones. We would be glad to give you a detailed list of the surveys.

[The information follows:]

Survey delays resulting from funding reductions in the past 2 years are as follows:
National survey of family growth—delayed from 1986 to 1987.
National health and nutrition examination survey—delayed from 1987 to 1988.
National mortality followback survey—delayed from 1985 to 1986.
National nursing home survey—delayed from 1984 to 1985. Additionally, the scope of this survey will not be as broad as would be necessary to address a number of known data needs.

SURVEY SAMPLE SIZE

Senator WECKER. Has there been any change in the sample size because of the budget reductions?

Dr. FEINLEIB. Yes; in our national health interview survey we had been sampling about 40,000 families each year in the United States. We were hoping to be able to sample some of the minority population starting this year, bringing the sample up to 50,000. We are maintaining the sample size at 40,000 rather than expanding as we had hoped to.

Senator WECKER. During yesterday's hearing with Secretary Heckler we discussed the recently published "Hunger in America" report that estimated that 20 million Americans suffer from hunger.

I have also seen a report issued by the Joint Subcommittee on Human Nutrition Research that describes the status and the plans for research in nutrition supported by the Federal Government.

You are requesting $4.4 million for a national health and nutrition survey. Will it duplicate or enhance the other studies I have just mentioned?

Dr. FEINLEIB. It will enhance those other studies. We will be trying to coordinate these activities with the surveys of the Department of Agriculture. We will be obtaining information about the health status, nutritional status, of a wide variety of the population of the United States.

The most difficult area to sample are the people that may be most susceptible, such as minorities and the impoverished, but we are making a strenuous effort to try to get full samples.

Senator WECKER. When do you expect the results from your survey?

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Dr. FEINLEIB. If we can get it into the field in 1988, we think the first data will be available about 1991.

Senator WEICKER. Why would we have to wait until 1988?

Dr. FEINLEIB. It takes approximately 2 years to plan the full sampling frame and develop the survey instruments, test them, develop the mobile clinics that have to go out and do the sampling. That is where we have been trying to get the planning going.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions, Dr. Mason, for response to the record. I thank you for your appearance. Other Senators also could very well submit questions for response to the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

HEALTH PRIORITY FOR THE NATION

Question. Dr. Mason, you are a physician are you not? I would expect that as Director of the Centers for Disease Control you have a very good understanding of the needs of this Nation--in fact the world-- for the intense efforts necessary in the areas under the jurisdiction of the Assistant Secretary for Health.

The Committee is very interested in hearing your assessment of these needs. Could you briefly summarize them for us now, and provide a more detailed evaluation for the record.

Answer. The mission of the Public Health Service (PHS) is to help protect and improve the health of the American people and to help assure access to reasonable health care at reasonable cost. The activities of the Federal government are conducted in concert with the private sector.

In responding to this challenge, PHS has placed primary emphasis on the need for biomedical research and increased efforts in disease prevention and health promotion.

The needs of the American people can be categorized in terms of the various life stages. In terms of infant health the focus is on reducing infant mortality. Increased understanding of the importance of prenatal care is a special area of emphasis. Our goal is to reduce infant mortality by 35 percent by 1990.

Programs to improve child health by fostering optimal childhood development deserve considerable attention. Our goal is to reduce deaths among children by at least 20 percent. The adolescent and young adult life stage presents a number of opportunities for improvement. For example, PHS is working to address smoking, alcohol and drug abuse problems which obviously have a significant impact on the adolescent health status. Our goal is to reduce deaths among young people ages 15 to 24 by at least 20 percent.

The adult life stage involves many challenges and it is hoped that our efforts will reduce deaths among people in this life stage by at least 25 percent by 1990.

The needs of aging adults involve not only improving health but also improving the quality of life for older adults.

The emphasis on biomedical research will contribute to changes at every life stage and our health promotion and disease prevention activities can influence all of the American people.

Question. Putting the National budget difficulties aside for the moment, are we putting enough resources into these efforts, and more specifically where would you place additional resources if you had them?

Answer. Although the budget difficulties have affected most Federal government activities, I believe that PHS has been successful in establishing the proper priorities for distributing

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resources. We carefully evaluate research opportunities and dedicate the available financial support to those activities with the greatest potential.

Our emphasis on health promotion is an effort to inform the public about beneficial lifestyle changes that can be made to improve health.

I believe that PHS is addressing the important health issues as effectively as possible and we will continue to allocate resources to these high priority activities.

1986 BUDGET REQUEST

Question. The President's budget request for the Office of the Assistant Secretary for Health totals $105,155,000. What was the amount requested by you or your predecessor, Dr. Brandt, to the Secretary?

Answer. The 1986 budget request to the Department for this appropriation totaled $167.7 million.

Question. Can you tell us which accounts, if any, received reductions in negotiations with the Department? With OMB?

Answer. There was a total reduction of $62.6 million, $23.2 million by the Department and $39.4 million by the Office of Management and Budget. Those reductions were made in the various accounts as follows:

- National Center for Health Services Research and Health Care Technology Assessment - There was a total reduction of $11.6 million--Department Reduction, -$5.1M; OMB Reduction, -$6.5M.
- National Center for Health Statistics - The reduction in this account was $22.4 million--Department Reduction, -$18.1M; OMB Reduction, -$4.3M.
- Adolescent Family Life - The reduction in this account totals $3.9 million and was an OMB reduction.
- PHS Termination Expenses - The Office of Management and Budget eliminated $15.5 million requested for expenses related to the reduction of 1,484 in FTEs for the Public Health Service in 1986.
- National Youth Sports - The request of $5.7 million was deleted by OMB.
- PHS Management - The reduction in this account totaled $2.3 million and was an OMB reduction.
- Smoking and Health and the Disease Prevention and Health Promotion activities - There was a reduction of $1.2 million for intervention programs and preventive services in these activities which was an OMB reduction.

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1990 PREVENTION OBJECTIVES

Question. Your statement indicates that OASH will be refining your prevention objectives for the year 1990. The original announcement mentioned specific measurable objectives in 15 disease and prevention priority areas.

Does your refinement of these objectives mean the Public Health Service is lowering its sights?

Answer. No, the Public Health Service is not lowering its sights for the 1990 prevention objectives. We are undertaking a comprehensive assessment of what refinements should be made in order to enhance our efforts in obtaining the objectives.

In 1985 PHS is undertaking a mid-course review of the 1990 objectives to look at where we are relative to attaining the objectives in the 15 priority areas and to identify new activities or efforts which would facilitate attainment of the objectives.

First, we are determining whether any of the existing objectives are misstated. That is, is there a better way to phrase the objective so that we can address the target more specifically. Second, we are identifying where changes should be made to redirect the program activities of the Public Health Service in order to improve the prospects for obtaining the objectives. Third, we are looking at what kinds of objectives we ought to begin considering for the year 2000.

Question. Has the Department's request for a decrease in NIH activities affected these objectives for 1990?

Answer. No, the Department's request for the National Institutes of Health (NIH) has not affected the 1990 Objectives.

Question. How much is NIH spending on disease prevention research?

Answer. In 1985 it is estimated that NIH will spend $1.209 billion and the President's budget for 1986 requests $1.144 billion for prevention research at NIH.

Question. How much is being spent Department-wide on prevention, and where are these programs located?

Answer. The 1986 budget request includes $3.3 billion for core support of the Department's prevention activities. These funds will be used primarily for research, disease control, and health promotion efforts. This figure is not all inclusive, however, for two reasons. First, a number of programs, such as Medicaid, provide preventive health services, but current reporting systems cannot identify the specific sums spent for these services. Second, in order to provide maximum flexibility to the states, block grants to states do not require detailed reporting requirements. Therefore, funding for prevention activities within most of these grants cannot be identified unless the activity is specifically designated for funding within the block grant.

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The following table reflects core prevention funds being spent by the Public Health Service (PHS), the Health Care Financing Administration (HCFA), the Office of Refugee Settlement, and the Office of Human Development Services (HDS). Total funding associated with two PHS block grants and one HDS state grants program is included in the total. All other block grants are excluded because the funding directly attributable to prevention activities cannot be determined separately.

HHS Prevention Funding
(Dollars in millions)

	FY 1984	FY 1985 Estimate	FY 1986 Request
PUBLIC HEALTH SERVICE:			
Food and Drug Administration:			
Total	$410.1	$410.3	$414.1 1/
Health Resources and Services Administration:			
Indian Health Service-Preventive Health Services.	61.6	65.2	38.8
Maternal and Child Health Block Grant	399.0	478.0	478.0
Family Planning	140.0	142.5	--- 2/
Subtotal	600.6	685.7	516.8
Centers for Disease Control:			
Total	380.5	408.3	392.6 1/
Preventive Health Services Block Grant/CDC (non-add)	(88.2)	(89.5)	(89.5)
National Institutes of Health:			
Prevention Research	1,063.7	1,209.2	1,144.5
Alcohol, Drug Abuse, and Mental Health Administration:			
Prevention Research	14.7	15.5	16.0
Office of the Assistant Secretary for Health:			
Smoking and Health	3.5	3.5	3.5
Disease Prevention/Health Promotion	2.5	3.6	3.5
Physical Fitness and Sports	1.1	1.4	1.4
Adolescent Family Life	14.9	14.8	14.7
Subtotal	22.0	23.3	23.1
Subtotal, PHS	$2,491.6	$2,752.3	$2,507.1
HEALTH CARE FINANCING ADMINISTRATION: (Federal Share of Costs)			
Medicaid:			
Family Planning	$155.0	$170.0	$180.0
Early Periodic Screening Diagnostic and Treatment (EPSDT)	45.0 3/	50.0 3/	55.0 3/

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(Dollars in millions)

	FY 1984	FY 1985 Estimate	FY 1986 Request
Medicare:			
Pneumococcal Vaccinations...	45.0	50.0	55.0
Prevention Research.....	0.7	0.7	0.7
Subtotal, HCFA.....	$245.7	$270.7	$290.7
OFFICE OF REFUGEE RESETTLEMENT:			
Preventive Health.....	$8.4	$8.4	$9.0
HUMAN DEVELOPMENT SERVICES:			
Administration on Aging:			
Nutrition-Congregate and Home Delivered Meals.....	$388.6	$403.9	$403.9
Administration on Children, Youth and Families:			
Head Start (Nutrition and Health Services).....	116.1	125.6	125.6
Child Abuse and Neglect State Grants.....	6.7	9.0	12.0
Subtotal, HDS.....	$511.4	$538.5	$541.5
TOTAL, HHS PREVENTION.....	$3,257.1	$3,569.9	$3,348.3

1/ Obligations

2/ In 1986 the Family Planning Program is proposed for inclusion in the Primary Care block grant. Funds for primary care services shall be distributed among the States in the same proportion as funds were distributed in FY 1985 under Section 1001 of the PHS Act.

3/ Screening expenditures only. Expenditures for treatment cannot be separately identified.

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES

Question. In last year's budget you requested $808,000 and 19 positions for the Uniformed Services University of the Health Sciences. I understand that this university is a source of MDs for the Public Health Service. I don't see that program in this year's budget request. Is this program being phased out?

Answer. Support for the Uniformed Services University of the Health Sciences in the Office of the Assistant Secretary for Health is being phased out. This activity is no longer shown as a separate budget activity. The resources for the students still being supported are included in the PHS Management activity. It should be noted that University is not a primary source of MDs for the Public Health Service.

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Question. If so, please explain your reasoning?

Answer. The phaseout of this program was based on a projected surplus of physicians by 1990. The staffing needs of the Public Health Service are being met through other methods of recruitment. The individual PHS agencies may, at some future time, decide to support students at the Uniformed Services University of the Health Sciences if a need arises.

PROPOSED RESCISSION

Question. You are proposing a rescission of $493,000 under Section 2901 of the Deficit Reduction Act. What specific budget functions will the money be taken from and what will be the impact of these reductions on your programs?

Answer. The proposed rescission will be distributed to the budget activities as follows:

National Center for Health Services Research and Health Care Technology Assessment	$30,000
National Center for Health Statistics	227,000
Adolescent Family Life	10,000
Smoking and Health	35,000
Disease Prevention and Health Promotion	25,000
Physical Fitness and Sports	13,000
PHS Management	153,000
Total	493,000

The proposed rescission of $493,000 from FY 1985 funds appropriated to OASH will reduce the scope of certain activities within the appropriation but will not significantly reduce the effectiveness of the program operations. The rescission of travel funds in the National Center for Health Statistics will limit staff travel for monitoring of contractors conducting data collection for surveys in the field. The rescission in the printing category will limit dissemination of certain health promotion publications. The other administrative areas affected by the rescission will be managed in order to minimize the impact of a reduced level of funding.

COORDINATION OF MEDICAL TECHNOLOGY AND PROCEDURES

Question. A number of agencies have responsibility for research regarding the safety and effectiveness of medical technology and procedures, in addition to the Center for Health Services Research. Specifically, NIH supports a number of clinical trials, mainly to assess new technologies and procedures. HCFA and PROPAC also play a role in this area.

What kinds of coordination or interaction occur between these agencies?

Answer. National Center for Health Services Research and Health Care Technology Assessment serves as the lead PHS organization in preparing recommendations to HCFA with respect to reimbursement coverage issues. At HCFA's request, the Center will perform assessments of the Scientific and Clinical issues germane

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to determining if a given technology is usual and necessary. NCHSR does not collect original data or conduct primary studies, but rather draws on data available from FDA and NIH in addition to information provided by manufacturers or presented in the literature. NIH and FDA as well as other PHS agencies review when appropriate, our assessment and findings.

There is extensive coordination between PHS and HCFA with regard to extramural research activities in the area of technology assessment. Because NIH processes receipt of grant applications for us on a contractual basis, we have an effective mechanism for coordination with them. The PROPAC research agenda is under development and discussions have been held with Dr. Altman, the Chairman, and with Dr. Steinwald, the Deputy Staff Director of PROPAC, to discuss how to enhance the complementarity of our research programs.

Question. What role do you see NIH playing in support of the Center's mission of assessing new and existing technologies and procedures?

Answer. We see the role of NIH as continuing to fund clinical trials, which we consider one of the fundamental building blocks of health care technology assessment. In addition, we anticipate that much of the longitudinal data on large cohorts of individuals which has been collected for various NIH investigations could be used by NCHSR to evaluate the effectiveness and cost-effectiveness of specific therapeutic interventions.

We also anticipate that the Office of Medical Applications of Research (OMAR) will continue to serve as a liaison between the Center's Office of Health Technology Assessment and the Bureaus, Institutes and Divisions of NIH, so that the benefit of clinical knowledge at NIH can be brought to bear on the Medicare coverage recommendation process.

TECHNOLOGY ASSESSMENT

Question. It is my understanding that the legislation that charged you with the additional responsibility of health care technology research and assessment also provided your office with a source of funds to conduct that research and assessment.

Yet the budget justifications do not mention that source of funding, and your budget request is $249,000 less that in FY 1985.

Dr. Mason, what is the maximum amount of funding that could be made available for technology assessment under the 1984 amendment?

Answer. The maximum amount of funding that could be made available for technology assessment is $4.8 million.

Question. How much of that amount will you receive?

Answer. $1.5 million has been made available to NCHSR/HCTA.

Question. Please explain the reasons for the differences.

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Answer. The source of funds referred to in the legislation is Section 2113 of the PHS Act. This section, which gives the overall authority for evaluation, states that "such portion as the Secretary may determine, but not more than 1 percentum... shall be available for evaluation..." Although the Secretary may use up to 1 percent for evaluation, the amount actually used has always been less than 1 percent. In previous years the total 1 percent availability ranged from $55-$60 million., However, only $15-$20 million of that has been used. A calculation based on the total one percent availability of $60 million would yield a 7½ percent amount of $4.8 milion. Using planned obligations as a base would yield a 7½ percent amount of $1.5 million.

It is important to note that the 1 percent evaluation set-aside is not a separate account. The funds come from most of the line items in PHS appropriations. The 7.5 percent provision increases the amount of agency money which is used for evaluation which results in less money available to the program for which the funds were appropriated. The decision to provide $1.5 million for technology assessment enables us to comply with the 7.5 provision without adversely affecting the PHS agency activities.

Question. Please provide for the record a detailed analysis of: a) Your funding requirements for maximum operations in the area of technology assessment. b) Any correspondence that may have occurred within DHHS and between DHHS and OMB concerning this funding, research and assessments mandated under the 1984 amendment.

Answer. a) The technology assessment responsibilities of the Center were expanded as a result of the recently enacted reauthorization. The funding requirements in FY 1986 include certain functions which are earmarked in the new legislation. These requirements are:

-- $750,000 must be spent on a grant to the Institute of Medicine to continue funding the Council on Health Care Technology.

-- not less than $3,500,000 shall be spent on technology assessment activities which includes the research grant activity, the National Advisory Council on Health Care Technology Assessment; and the Office of Health Technology Assessment which makes recommendations for PHS to HCFA on reimbursement under Medicare for technologies.

Within the budget request for FY 1986, the Center will support technology assessment activities to comply with the requirements listed above.

b) We are not aware of any correspondence occurring within DHHS or between DHHS and OMB concerning funding for research and assessments mandated under the 1984 amendments.

MEDICARE'S PROSPECTIVE PAYMENT SYSTEM

Question. A preliminary report from GAO indicates that Medicare's Prospective Payment system may be forcing patients out the hospital too soon.

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What are you doing to evaluate the efforts of the new Medicare DRG-based prospective payment system?

Answer. The major focus of the National Center's work on the effects of the Prospective Payment System (PPS) is the Division of Intramural Research's Hospital Studies Program (HSP). One of the main components of the HSP is the Hospital Cost and Utilization Project (HCUP). The HCUP data base contains hospital, patient, and county information for 384 short-term, general, non-Federal hospitals for 1970 through 1977. Information on general characteristics of physicians that can be linked to patient data has been obtained for a subset of 160 hospitals. Following the implementation of PPS, NCHSR/HCTA decided to extend the HCUP data to include information for 1980 through 1987. When these data are added, information will be available for three critical periods: the decade prior to changes in Medicare's approach to hospital reimbursement, the years when the payment system was governed by principles established by the Tax Equity and Fiscal Responsibility Act of 1982, and the period during which PPS was being implemented. The sample will be enlarged to approximately 500 hospitals. Recruitment of hospitals for the study is in progress and should be completed by April 1985.

Our current projection is that the hospital data for 1980 through 1983 should be usable by December of 1985, with 1984 data incorporated by February 1986. Patient data for 1980-1984 should be added by August of 1986. Physician characteristics data for the subset of 160 hospitals is based on 1983 AMA data and is now assembled. County level data is currently available through 1981, and by December, data for 1982 will have been added.

Another notable PPS-related effort of the Hospital Studies Program is the Hospital Cost and Clinical Research Project (HCCRP). This study which is being conducted with the National Cancer Institute (NCI) of NIH, is designed to test the hypothesis that PPS will adversely affect clinical trials for cancer research. The study will address three specific questions: First, are there significant cost or resource use differences between cancer protocol and nonprotocol patients? Second, how do costs for protocol and nonprotocol patients compare with PPS fixed reimbursement rates? Even if protocol costs are higher on average, PPS payments may frequently cover these costs outright or through adjustments for specific hospitals, e.g. teaching hospitals. Third, aside from what can be predicted with early data in answering the first two questions, what are the actual effects of PPS on care for cancer patients and on the willingness of hospitals to participate in clinical trials? The study will examine data for the years 1980-1985. It is estimated that the first two HCCRP analyses--a length of stay analysis and a preliminary charge analysis--will be completed during fiscal year 1986. Completion of three additional analyses is currently projected for March, 1988.

LONG TERM CARE

Question. As America grows older, the problem of providing and paying for long-term care for the "frail elderly" will become more acute. Do you have any plans to study the "Long Term Care" problem?

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Answer. Three major NCHSR/HCTA research activities in the area of long term care can assist decision-makers as they undertake policy analyses in developing new programs.

- Under a grant from NCHSR/HCTA's Extramural Division, researchers developed a new approach to home care for the elderly who are homebound and chronically ill: a team consisting of a physician, a geriatric nurse practitioner, and a social worker providing round-the-clock, on-call medical care to patients in their homes. A randomized, controlled trial showed that the approach provided effective, less costly care to the terminally ill. Aged patients treated by the team, but who died during the course of the study, received more services at home and were hospitalized about half as much during their final two weeks as patients in the control group. Costs of home care provided by the team were higher than costs of traditional home care because more services were provided. Yet overall costs for the patients treated by the team were about a third less than total costs for patients receiving traditional at-home care, owing to decreased hospitalizations. In addition, satisfaction with the care was significantly greater among team care patients, and especially among their family members.

- Intramural researchers at NCHSR/HCTA continue to examine the potential for increasing private financing of long term care through private insurance. Prototype insurance policies have been developed that will serve as the basis for stimulating alternative premium estimates. Consumer interest is being assessed by a survey of Medicare beneficiaries. (The survey is being done with the cooperation of HCFA, as an add-on to HCFA's ongoing study of Medicare supplemental insurance regulation.)

- Another intramural project is attempting to address the issue of the back up of potential nursing home patients in hospitals due to shortages of nursing home beds and low Medicaid reimbursement levels. This back up tends to be a particular problem for "heavy care" patients, because the cost of their care is typically more than what will be reimbursed. This NCHSR study is attempting to determine whether nursing homes will respond to a payment system which provides incentives for the admission of more heavy care patients.

Question. I understand that NCHSR's original budget request included funding for 50 new starts in your extramural research program, but that this request was turned down at the Department level. If you had received approval for this additional funding, how would you plan to use it?

Answer. We would have used that money to look at a number of issues, including the development of methodologies for looking at cost-benefit and cost effectiveness of various technologies. We would have been able to support studies that looked in addition at

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the small area variation question and some studies of effects of prospective payment on the health care delivery system. We are carrying out some of those kinds of activities within our regular appropriation. Since we are speaking here about an investigator-initiated extramural research grant program, it is hard to specify exactly what additional projects might be funded because they have to go through the peer review system.

HEALTH STATISTICS - BUDGET REQUEST

Question. Your budget request reflects an increase of $5.4 million, and a decrease of 14 full-time equivalents for the National Center for Health Statistics. Please explain the request for an increase in funding.

Answer. NCHS conducts over a dozen surveys and data systems; some of these are conducted continuously, while others enter their data collection phase in accordance with a periodicity schedule. The NCHS budget varies from year to year depending on the cycles of these systems. Most of the $5.4 million increase for FY 1986 ($4.4 million) is for planning and development for the next cycle of the National Health and Nutrition Examination Survey (NHANES), which is scheduled to begin data collection in 1988. This survey, last conducted from 1976-81, is an important source of data on the health and nutritional status of the general population, based on extensive physical examinations, X-rays, laboratory tests, and interviews. NHANES is also an integral component of the National Nutrition Monitoring System.

The balance of the increase will allow for continued planning and a pretest for the National Survey of Family Growth, maintenance of the current Federal share of costs of the National Vital Statistics System, and implementation of a new design for the National Hospital Discharge Survey. The increase also includes $.2 million to obtain linked birth and infant death records from the States.

HEALTH STATISTICS - STAFFING LOSSES

Question. How do you plan to absorb the loss of 14 positions in 1986 after a loss of 23 positions in 1985 without a negative effect on programs?

Answer. NCHS will absorb the decrease of 14 FTE's primarily through attrition and through contracting out for some activities previously conducted by NCHS staff. Reductions in personnel ceilings are being made as part of a more general, government-wide effort to reduce personnel and associated costs, and it is difficult to predict the specific impact of the reductions on NCHS programs.

Question. How much was the Center's budget request to the Department for FY 1986?

Answer. NCHS requested a total of $70.4 million.

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NCHS SURVEYS

Question. What significant health surveys will the National Center for Health Statistics be conducting or supporting during FY 1986? What survey plans have been postponed because of budgetary limitations imposed upon the Center by the Department or OMB?

Answer. The following surveys and data systems will be in their data collection cycle during FY 1986:

- o National Vital Statistics System. NCHS administers activities to produce statistics on live births, deaths, fetal deaths, abortions, marriages, and divorces. Important data from the system include infant mortality rates, causes of death, and life expectancy.

- o National Death Index (NDI). The NDI is a central, computerized index of information from death records established as an aid to epidemiologists and other researchers in establishing the vital status of individuals under study.

- o National Health Interview Survey (NHIS). The NHIS is a principal source of information on health, illness, and disability status of the population. Each year, the survey consists of a "core" set of questions on health, socioeconomic, and demographic items as well as one or more sets of supplemental questions to obtain more detailed information on issues of current concern.

- o National Nursing Home Survey. This survey provides information on nursing homes from two perspectives--that of the provider of services and that of the recipient. Data about the facilities include basic characteristics such as size, ownership, Medicare/ Medicaid certification, occupancy rate, days of care provided, and expenses. For patients, data is obtained on demographic characteristics, health status, services received and the outcomes of such care.

- o National Hospital Discharge Survey. This survey obtains data on the characteristics of patients, their expected sources of payment, lengths of stay, diagnoses and surgical operations, and patterns of use of care in hospitals of different sizes and types of ownership in the four geographic regions in the country. Data from this survey is useful in monitoring specific diseases, the introduction of new technologies, and the impact of changes in the financing system.

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The FY 1986 request will also support the planning, pretesting, analysis, or other phases of the following periodic surveys:

- National Ambulatory Medical Care Survey (NAMCS). The NAMCS collects information about ambulatory medical care provided by office-based physicians. This survey provides statistics on the demographic characteristics of patients and on services provided, including information on diagnoses, diagnostic procedures, patient management, and planned future treatment.

- National Survey of Family Growth (NSFG). The NSFG is designed to provide national statistics on the fertility, family planning, and reproductive health of American women in the childbearing years. For example, recent data from the NSFG has documented the shift in birth control practices, finding that sterilization is currently the leading method among married couples.

- National Health and Nutrition Examination Survey (NHANES). NHANES collects nutritional, physiological, and diagnostic data through specially designed standardized health examinations. These direct examinations, including clinical tests and measurements, are the only source of diagnostic data regarding unrecognized and untreated diseases, and are the best source for standardized clinical, physical, and physiological data on the U.S. population. NHANES is also an integral part of the National Nutrition Monitoring System.

- Hispanic Health and Nutrition Examination Survey (HHANES). The HHANES is a special, one-time study of the Hispanic population in three areas of the U.S.: Mexican-Americans residing in the Southwest; Cuban-Americans in the Miami, Florida area; and Puerto Ricans in the New York City area. Modeled after the NHANES survey, the HHANES has examined approximately 12,000 persons, representing the first large scale health survey of Hispanics. Data collection was completed at the end of 1984; data analysis and publication of results will continue into FY 1986.

- National Medical Expenditure Survey. Building on related surveys conducted in 1977 and 1980, NCHS (in close collaboration with the National Center for Health Services Research/HCTA and the Health Care Financing Administration) is planning a 1987 survey to address health care cost, expenditure, and utilization issues.

NCHS also conducts a number of surveys that are primarily supported by reimbursements from other Public Health Service agencies, including the National Mortality Followback Survey and the NHANES I Epidemiologic Followup Study.

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No NCHS surveys will be delayed or postponed as a direct result of funding levels in the FY 1986 request.

Question. What cutbacks, if any, have been made in the frequency and scope of NCHS national surveys over the last two years because of funding reductions?

Answer. The following surveys have been adjusted due to reasons of fund or personnel availability.

- o National Survey of Family Growth (delayed from 1986 to 1987)
- o National Health and Nutrition Examination Survey (delayed from 1987 to 1988)
- o National Nursing Home Survey (delayed from 1984 to 1985)
- o National Mortality Followback Survey (delayed from 1985 to 1986)

The scope of the National Nursing Home Survey will not be as broad as would be desired to address a number of known data needs.

NCHS - NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY

Question. During yesterday's hearing with Secretary Heckler we discussed the recently-published Hunger in America Report that estimated that 20 million Americans suffer from Hunger.

I have also seen a report issued by the Joint Subcommittee on Human Nutrition Research that describes the status and plans for research in nutrition supported by the federal government.

You are requesting $4.4 million for a National Health and Nutrition Survey.

What will that survey accomplish?

Answer. The National Health and Nutrition Examination Survey (NHANES) is national in scope, based on probability sampling, and collects a broad range of morbidity data and related health information. NHANES, as an examination survey, differs from other national surveys in that it is primarily concerned with those kinds of health-related data obtained only (or at least optimally) from specially standardized direct medical examinations, including tests and other procedures used in clinical practice. Such examinations given to persons selected in the scientific sample permit estimates of the prevalance of specifically defined diseases in the U.S. population, including cases not previously identified. They also permit estimation of the distribution within the population of a broad variety of nutrition- and health-related measurements, including not only physical measurements such as height, weight and various skinfolds, but also physiological measurements, such as diastolic blood pressure and serum cholesterol level and measurements of physical fitness.

Question. Will it duplicate or enhance the other studies I just mentioned?

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Answer. The third National Health and Nutrition Examination Survey will enhance information available from other Federal and State agencies and private organizations. NHANES is a principal component in the National Nutritional Monitoring System, an intergovernmental effort to coordinate the collection and analysis of data on nutrition. Through a variety of mechanisms, NCHS coordinates its nutrition-related data systems with the Department of Agriculture and with other Public Health Service agencies.

Question. When was this survey conducted in the past?

Answer. During the years 1959-85, the National Center for Health Statistics (NCHS) conducted six separate examination surveys. The first of these, the National Health Examination Survey, Cycle I, (NHES I) focused on the prevalence of selected chronic diseases in civilian noninstitutionalized U.S. adults aged 18-79. The next two surveys, which were conducted from July 1963 through March 1970, were largely devoted to the growth and development of children 6-11 (the National Health Examination Survey, Cycle II--NHES II) and 12-17 years of age (the National Health Examination Survey, Cycle III--NHES III). The fourth survey introduced a new emphasis. In 1969 the Department of Health, Education and Welfare established within NCHS a continuing activity to measure the nutritional status of the U.S. population and to monitor changes in status over time. The name of the survey conducted during 1971-75 was changed to the National Health and Nutrition Examination Survey (NHANES I) to reflect the new emphasis. It was followed by the second National Health and Nutrition Examination Survey (NHANES II) in 1976-80. Most recently in 1982-84 a related survey, the Hispanic Health and Nutrition Examination Survey (HHANES), was conducted to determine the health of Mexican-Americans, Puerto Ricans and Cuban-Americans residing in the continental United States.

STUDY ON HUNGER

Question. Did you participate in either the Study on Hunger or Nutrition Research Study?

Answer. The National Center for Health Statistics did not participate in the task force which produced "Hunger in America." NCHS participated in the work of the Joint Subcommittee on Human Nutrition Research, a committee established by the Office of Science and Technology Policy, and currently participates in a number of interagency panels related to nutrition and nutrition monitoring research.

Question. Are you a member of the Interagency Committee on Human Nutrition Research?

Answer. The Department is represented on the Interagency Committee on Human Nutrition Research. The Assistant Secretary for Health, HHS, shares the chairmanship of the Committee with the Assistant Secretary for Science and Education, USDA.

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DHHS EXPENDITURES ON SMOKING AND HEALTH

Question. Can you tell this Committee what the total spending level for Smoking and Health is for the Department of Health and Human Services.

Answer. The Department will be spending approximately $38.8 million in 1986 to combat smoking and understand its destructive effects on health. Principal participants are the Office on Smoking and Health, the National Institutes of Health, the Alcohol, Drug Abuse, and Mental Health Administration, and the Centers for Disease Control.

PHS Smoking and Health Activities
(dollars in $000)

	1984	1985	1986 Request
NIH			
Cancer	$15,918	$20,351	$21,457
Heart, Lung & Blood	7,300	8,150	7,850
Environmental Health	1,107	1,167	1,215
Child Health	1,677	1,900	1,900
Research Resources	659	745	662
NIH, Subtotal	26,661	32,313	33,084
ADAMHA			
Drug Abuse	1,447	1,700	1,800
OASH			
Smoking and Health	3,521	3,503	3,503
CDC			
Chronic & Environmental Health	357	375	375
PHS Total	$31,986	$37,891	$38,762

GOVERNMENT SPENDING ON TOBACCO SUBSIDIZATION

Question. How much is the government spending to subsidize and encourage the production of tobacco? Please provide the Committee a detailed response to this question for the record.

Answer. The most current information we have is from the United States General Accounting Office's reply to a request from Congressman Petri for cost information on the U.S. Department of Agriculture's tobacco program. According to the GAO report on the 1982 crop year, flue-cured tobacco valued at $437.4 million and burley tobacco valued at $498.1 million were under loan.

Carrying costs totaling $52.3 million and interest costs totaling $39.9 million had accrued on crop year 1982 flue-cured tobacco during July 1982 through June 1983. On crop year 1982 burley tobacco, carrying charges totaling $52.7 million and interest charges totaling $23.9 million had accrued during November 1982 through June 1983.

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The Department of Agriculture's Office of Budget and Program Analysis estimated administrative and other service costs to operate the tobacco price-support program to be $116.5 million for the 4-year period 1981 through 1984.

IMPLEMENTATION OF COMPREHENSIVE SMOKING EDUCATION ACT

Question. What is the status of the implementation of the 1984 Comprehensive Smoking Education Act?

Answer. The "Comprehensive Smoking Education Act" of 1984 (P.L. 98-474) was enacted on October 12, 1984. The Act calls upon the Department to begin monitoring and evaluating cigarette additives; requires a biennial comprehensive report to Congress on Federal and private sector activities to inform the public of the health consequences of smoking; and establishes an Interagency Coordinating Committee on Smoking on Health to coordinate all Federal and private sector research and educational activities on the health effects of smoking. The provisions of the Act having to do with the four rotational cigarette warning labels fall under the jurisdication of the Federal Trade Commission.

In 1985 implementation activities have focused on developing a process to monitor cigarette additives; preparing the required Congressional report; and organizing the Coordinating Committee. At the present time all necessary paper work needed to establish the Coordinating Committee has been prepared and submitted to the Secretary for approval. We expect this Committee to be operational later in 1985.

In 1986, all of the requirements of the Act will be implemented. Cigarette additives will be monitored and evaluated. Written procedures to assure the confidentiality of information provided by persons who manufacture, import or package cigarettes with respect to these additives will be established. The information shall be treated as a trade secret. In addition, the Coordinating Committee will meet at least four times a year to assist in the development of materials for the comprehensive report to Congress on Federal and private sector activities.

Question. What have cigarette manufacturers done so far in preparing for the inclusion of the four new warning labels on cigarette packages and advertising on a quarterly rotation basis?

Answer. The implementation of this section of the "Comprehensive Smoking Education Act" falls within the jurisdiction of the Federal Trade Commission (FTC). On February 4, 1985, the FTC published a notice in the Federal Register requiring manufacturers and importers to submit plans on how they will comply with the legislation requiring rotational warning labels. Submission deadline for such plans is May 6, 1985. We do not expect to have further information on this facet of the legislation until all plans are received and approved by the FTC.

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Question. What are the prospects of manufacturers implementing this requirement successfully by October 1985 as mandated by the legislation?

Answer. The Federal Trade Commission has given cigarette manufacturers and importers until May 6, 1985 to submit plans on how they propose to implement this requirement. This should allow sufficient time for the manufacturers and importers to have approved plans fully in place by October 1985 as mandated.

Question. How will the $390,000 that you are requesting be used?

Answer. The $390,000 requested for 1986 will fully implement the recently enacted "Comprehensive Smoking Education Act" of 1984. The funds will be used for monitoring and evaluating cigarette additives; compiling and making available information on State and local laws relating to the use and consumption of cigarettes; developing the mandated report to Congress on Federal and private sector activities to inform the public of the health consequences of smoking; and supporting the Interagency Coordinating Committee on Smoking and Health.

Question. What is the status of the implementation of the provision of the 1984 legislation that cigarette manufactures report annually to the Secretary on cigarette additives?

Answer. Section 7 of the "Comprehensive Smoking Education Act," which deals with cigarette ingredients, does not take effect until October 12, 1985, one year after the date of the Act's enactment. At present, the Department is setting up a review mechanism to comply with the provisions of the Act.

Question. What procedures have been established to assure the confidentiality of this information as required by the law?

Answer. Section 7 of the "Comprehensive Smoking Education Act," which deals with cigarette ingredients, does not take effect until October 12, 1985, one year after the date of the Act's enactment. The procedures necessary for compliance with the Act's confidentiality requirements are being developed by the Department.

PASSIVE SMOKING

Question. What is the status of the review of the issue of passive smoking as requested by this Committee? What has been done thus far to examine the health risks of passive smoke to nonsmokers? How many persons are working on this study and when can we expect to see a progress report?

Answer. The Office on Smoking and Health is developing a major review of the passive smoking issue. In doing so, it is utilizing a process similar to that used for the annual Surgeon General's Reports. This decision was made in consultation with the representatives of outside medical and scientific organizations and other experts. The effort will entail using the services of a number of expert consultants located within the Public Health

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Service and in the private sector. Following a review of draft chapters by subject-matter experts, the final review of the report will be undertaken by senior scientists.

NEW COOPERATIVE AGREEMENTS

Question. What new cooperative agreements to stimulate health promotion efforts with private and voluntary organizations are being supported in FY 1985? What types of Health Promotion efforts will these agreements support and what groups of people will they reach?

Answer. In FY 1985, we expect to award eight new cooperative agreements. Final determination of projects to be supported from among 58 applicants has not been completed. We expect, however, to support activities such as:

- development of a comprehensive information service for health promotion materials and programs for older Americans;
- testing and dissemination of a package of clinical preventive services for persons served by Preferred Provider Organizations (PPOs);
- packaging and dissemination of the 1990 Health Objectives for the Nation through public school systems;
- development of health promotion programs for low-income adolescents;
- assistance to State Health Departments in adapting 1990 Health Objectives for the Nation to their States;
- application of nutrition education and information as a form of health promotion in the workplace; and
- testing and dissemination of health promotion programs for public school system employees.

From this listing of activities, it becomes clear that the National Health Promotion Cooperative Agreement Program will be reaching a broad spectrum of people. This spectrum ranges from school age children and low-income adolescents to the elderly. The program reaches not only specific groups like public school employees, but also general populations either in their workplaces or through their sources of clinical medical services.

PHYSICAL FITNESS

Question. What is the status of the fitness of our youth compared to 25 years ago? Are our children in better shape now than they were then?

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Answer. New data which presents the status of fitness of today's youth compared to 25 years ago will be available August 1985. The Institute for Social Research at the University of Michigan is under contract to study fitness performance of a national sample of children and youth aged 10-17 compared to the same ages on the same test conducted in 1957, 1965 and 1975

Testimony presented at a series of six public hearings held in Los Angeles, Houston, Indianapolis, Denver, Boston and Washington, DC in 1984 indicated that fitness test scores are lower than those in the 1960s. These reports were from local and/or regional studies and did not represent national samples. The hearings were carried out with corporate sponsorship from the Campbell Soup Company.

Question. What percentage of schools maintain daily physical fitness and education activities for their students?

Answer. Although there is no nationwide reporting of enrollement in school subjects, a recent study of a sample of schools throughout the country shows that 36 percent of students in grades 5-12 are in physical education five days a week. Thirty-one percent, forty-three percent and forty-eight percent in grades 10, 11, and 12 respectively are not in physical education at all.

EMPLOYER SUPPORTED PHYSICAL FITNESS PROGRAMS

Question. Has any progress been made in recent years in encouraging employers to develop and support physical fitness programs for their employees?

Answer. In the past ten years, the number of employee fitness programs has gone from just a handful to several thousand. Over 500 major corporations today have full-time staff dedicated to managing comprehensive programs in fitness and health. Many other large corporations and smaller companies have turned to community resources such as YMCAs, park and recreation programs, health clubs and hospitals to obtain education and exercise program services for their employees. While many of the earlier programs were offered only to selected workers such as executives, the current trend is to make the programs available to all employees and sometimes dependents and retirees.

The Federal government believes worksite fitness programs are an important element in a strategy to promote the health of all Americans. Currently, the Office of Disease Prevention and Health Promotion and the Office of the Assistant Secretary for Planning and Evaluation are conducting a national survey of worksites with 50 or more employees to determine the prevalence of fitness and other health promotion activities in the worksite. The baseline data being collected should allow us to monitor progress in the future. The results should be released in the fall of 1985.

Other examples of federally sponsored efforts to increase worksite health promotion programs of which physical fitness is an important component include the following:

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The President's Council on Physical Fitness and Sports (PCPFS) has been very active in encouraging employers to take part in worksite fitness programs by securing corporate support to produce and distribute instructional materials including pamphlets, posters and films. PCPFS has also been involved with a series of conferences on fitness and health in the workplace which have provided an overview of health and fitness problems of working adults, available data on what programs at the worksite can do to combat these problems, and program models. The PCPFS also started the forerunner to the Association for Fitness in Business, an organization of fitness professionals who have an interest in worksite fitness programs. This organization has grown from 24 members in 1974 to around 3,000 members now.

The Office of Disease Prevention and Health Promotion (ODPHP) has been actively encouraging employee health promotion programs and sponsored the first National Conference on Health Promotion Programs in Occupational Settings in January 1979. Current ODPHP worksite activities include: a project to encourage labor participation in employee health promotion program implementation; an attempt to increase responsible reporting of programs in the business media; and a project which is exploring the future of work and health so that health promotion programs will begin to meet the needs of changing work environments.

The National Heart, Lung, and Blood Institute cosponsored with General Motors and Metropolitan Life Insurance Company a conference on the benefits of worksite cardiovascular disease control programs of which fitness programs are frequently a component. The meeting was well attended by corporate and government leaders.

The White House and the Department of Health and Human Services assisted the Health Insurance Association of America with a national teleconference for chief executive officers on worksite health promotion programs. President Reagan personally encouraged the corporate leaders to consider offering physical fitness and other health promoting programs for employees.

The Centers for Disease Control's Office of Health Promotion and Disease Prevention recently cosponsored a conference on international worksite health promotion. This event allowed senior level health officials such as Surgeon General Koop to share ideas with senior level health officials from countries such as Indonesia which has mandatory worksite exercise breaks.

The government is also serving as an example for the private sector by providing fitness programs to its employees. The program developed 15 years ago at the National Aeronautics and Space Administration is only one example of a model for both the public and private sector. The Federal Interagency Health and Fitness Council (FIH&FC) has provided a surge of activity for public employees by lending expertise from agencies at the federal, state and municipal levels. Operating under the auspices of the PCPFS, the FIH&FC assembles Fitness Implementation Teams (Fit Teams) which provide consultation on the development of fitness programs for employees to requesting agency administrators.

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PHYSICAL FITNESS PROGRAMS FOR PREGNANT WOMEN

Question. Has any attention been paid to developing physical fitness programs for pregnant women?

Answer. One of the early issues of Physical Fitness Research Digest was entitled "Physical Activity During Menstruation and Pregnancy". This publication was distributed to fitness leaders and researchers throughout the country.

Regional clinics on Physical Fitness and Sports have included sessions on fitness for pregnant women and for mothers and young children.

The 1984 First National Women's Conference on Physical Fitness presented by the PCPFS in cooperation with the Campbell Soup Company presented many important aspects of physical fitness and sports for women including a session on "Pre and Postnatal Exercises". This conference was designed as a general blueprint for follow-up conferences in the states.

A recent publication developed cooperatively with the U.S. Army is entitled "Family Fitness Handbook". This publication addresses the special needs of pregnant women in the area of physical fitness pregnant. This publication is used by the Army's physical fitness leaders at installations throughout the world.

RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

Question. Why are the cost of living adjustments (COLAs) for the retired pay for commissioned officers being delayed, and what will the impact be?

Answer. Consistent with government-wide effort to contain retirement cost increases, the Administration is proposing that the cost-of-living allowances for retired PHS Commissioned Officers scheduled for January 1986 be delayed until January 1987.

Postponement of the COLA will yield savings in PHS retirement payments of approximately $2.6 million in FY 1986.

Question. Please explain the budget request of $97.1 million and the increase of $25 million in this appropriation.

Answer. The 1986 budget request includes $67.7 million for retirement pay for an estimated 2,200 retirees; $3.4 million for survivor's benefits for an estimated 280 survivors; $9.8 million for medical care for an estimated 46,146 outpatient claims; and $16.2 million for a reserve fund to pay unanticipated program needs.

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The budget increase of $25.0 million includes $2.8 million for the annualization costs of additional retirees/survivors in 1985 as well as a net increase in the number of retirees/survivors during 1986; $0.5 million for the estimated increase in the costs of medical care; $5.5 million for an increase from 11 payments in 1985 to 12 payments for retirees and survivors in 1986; and, $16.2 million to establish a reserve fund required as a result of the proposed change from an indefinite to a definite appropriation.

Question. Your budget has an increase of $5.5 million and refers to 11 payments in 1985 and 12 payments in 1986. Please explain.

Answer. The $5.5 million increase in 1986 is required as a result of the one-time savings accruing in 1985 because of the change in the date of benefit payments from the last day of the month to the first day of the month. Because of this change, 11 payments will made during FY 1985. The change is pursuant to Title II, Section 2201 of the Deficit Reduction Act, P.L. 98-369.

The date was changed from December 31, 1984 to January 1, 1985. The month which actually generates the savings will be September 1985. The payment for September will be made Oct. 1, 1985. (FY 1986)

USER LIAISON PROGRAM

Question. The Committee report accompanying the FY 1985 appropriations bill expressed concern over the reduction in funds available to the User Liaison Program. The report directs that funding for this program not fall below the FY 1983 level. How much did the User Liaison Program receive in FY 1985? How much will it receive in FY 1986?

Answer. In FY 1985 the User Liaison Program will receive funding of approximately $1,213,000. It is expected that this level of support will be at a comparable or greater level in FY 1986.

HEALTH SERVICES RESEARCH ACTIVITIES

Question. What types of basic health services research activities will the NCHSR be supporting in FY 1986? How many of these will be long-term research projects?

Answer. NCHSR has identified four areas that are likely to be of primary importance in 1986 and the remainder of the decade. These are:

- Primary care/health promotion and disease prevention
- Technology assessment
- Role of market forces in health care delivery
- Unique operational and policy issues faced by State and local governments.

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In primary care/health promotion and disease prevention, NCHSR will support studies addressing the effectiveness of specific interventions such as efforts to modify patients' unhealthful behavior and the cost effectiveness of specific preventive or health promotion services in the primar care setting. Clinical and epidemiologic studies will focus on communities' requirements for primary care services, the kinds of health problems seen by practitioners, and the ways in which these problems are managed.

Technology assessment projects will concentrate on both new and established technologies. Specific areas will include the development, diffusion and utilization of medical technologies and the development of new methods for evaluating them. Little is known about the efficiency and safety of many existing medical technologies, and less is known about their cost effectiveness.

Studies on the role of market forces in health care delivery will involve several areas. Economic incentives and the supply of health care services include the impact of provider reaction to prospective reimbursement for services as well as alternative delivery systems in ambulatory care such as HMOs. The emerging multihospital systems and independent hospitals will be assessed on differences with respect to patient outcome, quality of care, and access to care. Studies will also examine the identifiable patterns and differences in the costs, funding scurces, quality of care, staffing, and arrangements in caring for the elderly. A wide spectrum of issues identified by State and local governments will be addressed including public hospitals, ambulatory care, long term care and chronic illness, and health manpower.

Research supported by NCHSR is basically long term, ranging from two to five years in length. These studies provide NCHSR with a solid health services knowledge base from which information can be provided to policy makers both immediately and over time. Equally important is the development of new methods for assessing patient care and technologies for the next generation of policy issues. Neither the development of a knowledge base nor the development of new methods can be done in the short term. However, because the results of the long term projects supported by NCHSR become available annually as the studies are completed, the ability of NCHSR to respond to policy questions is continually enhanced.

NATIONAL MEDICAL EXPENDITURES SURVEY

Question. When do you expect to be able to conduct the NMES, last conducted in 1980?

Answer. Data collection for the National Medical Expenditure Survey will begin in January, 1987. Planning for this survey began in FY 1984. We anticipate OMB preliminary clearance will be obtained by September, 1985 and a contract for data collection will be awarded in January, 1986. The first reports from this survey of how Americans use and pay for their medical care will be available in spring, 1988. The full data set will be available by 1990.

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TECHNOLOGY ASSESSMENT APPLICANTS

Question. What steps have you taken to implement this Committee's recommendation that priority be given to investigator initiated grant applications that address technology assessment? How many applications for research support related to technology assessment were received in FY 1985?

Answer. We focused our efforts on technology assessment research and stimulated 45 applications; compared to 34 in FY 1984. Of these applications, we expect that 8 will be approved and funded in FY 1985. In addition, 15 continuation projects will be funded in FY 1985. As of this date, seven technology assessment projects are scheduled to receive FY 1986 continuation awards.

Of the 12 new starts we expect to be able to fund in FY 86, half of them will be in the high priority area of technology assessment. The new starts cannot of course be identified as yet.

REDUCTION IN THE PHS MANAGEMENT ACTIVITY

Question. What will be the impact of the $1.8 million reduction in the Public Health Service Management activity on the direction and management function in the Office of the Assistant Secretary for Health?

Answer. There will be a decrease of 39 FTEs in 1986, reflecting a ten-percent administrative reduction. The budget request will permit this acitvity to maintain an effective overall management capability for OASH and to provide leadership and direction for the Public Health Service Agencies. A review will be conducted of a variety of management and administrative functions and steps will be taken to assure that the greatest economies and efficiencies are realized.

MULTIPLE SCLEROSIS

Question. It has come to our attention from the National Multiple Sclerosis Society that multiple sclerosis is a disease with respect to which there are many existing and new therapies whose value is highly questionable or at least undetermined. Some of these therapies are also applied to other related diseases, and they are costing Medicare and Medicaid substantial amounts of money. Would research into such questionable therapies be within the mission of the Center under the 1984 amendments? How should that research be financed and how should its results be used?

Answer. Multiple sclerosis is a chronic disease of unknown cause for which there is no established means of proving the diagnosis during life. Its variable and unpredictable course is characterized by steady progression, stabilization, episodes of exacerbation and remission, and therefore it represents a good example of the kind of illness about which health services research and technology assessment efforts can contribute important information concerning diagnostic and therapeutic as well as economic and social issues.

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In the area of diagnosis, for example, the field of health services research includes studies of the information gain and the cost-effectiveness of new diagnostic technologies, such as Magnetic Resonance Imaging or Positron Emission Tomography, as well as the development of methods to assess and compare severity of illness. An extraordinary variety of treatments have been suggested for diseases like multiple sclerosis, ranging from snake venom to lettuce diets; this agency has completed assessments of two technologies recently proposed for treating multiple sclerosis - hyperbaric oxygen therapy and apheresis - and has determined that the published results do not support claims of effectiveness.

Because the course of chronic diseases such as multiple sclerosis is highly variable, the effects of different treatments cannot properly be determined by anecdotal information or case studies. Health services research has led to the design and development of disease registries - "data banks" - which have been shown to be particularly useful in evaluating the results of different regimens for managing such illnesses. Furthermore, several investigators in this field have succeeded in constructing and validating a number of health status indexes and measures of functional disability which are essential for assessing the immediate and long-term results of treatment. Other ways in which health services research can provide additional information for continuing discussion of these issues include studies of the effect of different system configurations or reimbursement methods on treatment practices, variations in the types and the quality of care given by different types of health care providers, and assessment of the social and economic effects of these diseases on families, communities, and public agencies.

INCREASE OF $3 MILLION

Question. Please explain the reason for your request for an almost $3 million increase in the Public Health Service Management budget.

Answer. The $3 million increase is a net change including an increase of $5.4 million for the National Center for Health Statistics and decreases of $2.4 million, which primarily reflects the reduction of 39 FTES and $1.8 million in the PHS Management activity. The increase for the National Center for Health Statistics provides funding for the next cycle of the National Health and Nutrition Examination Survey.

UnAUTHORIZED PROGRAMS

Question. Are there any OASH programs unauthorized in 1986?

Answer. Yes. The Adolescent Family Life Program requires reauthorization in 1986.

Question. If so, will you be proposing authorizing legislation?

Answer. Yes. New authorizing legislation to extend this program is being proposed.

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TECHNOLOGY ASSESSMENT EXPENDITURES

Question. Please provide the Committee with expenditures for Technology Assessment for the years 1980-1986.

Answer. The information follows. These figures reflect technology assessment research only.

1980	$1,710,000
1981	4,490,000*
1982	2,702,000*
1983	2,970,000
1984	2,998,000
1985	2,149,000
1986	2,149,000 (Projected)

* Figures for 1981 and 1982 include all projects funded by National Center for Health Care Technology.

RESEARCH FINDINGS ON COST AND DELIVERY OF HEALTH CARE

Question. What effect, if any, did research findings in this area have on cost and delivery of health care?

Answer. The National Center for Health Services Research and Health Care Technology Assessment has funded numerous assessments of technologies and procedures that affect the health care of millions of Americans. Research grants have been supported in areas including studies of methodological issues, practitioner behavior, assessment of specific technologies, clinical indicators/protocols, technology diffusion, and clinical decision making. These studies have resulted in findings that are of major importance in reducing the cost of care while maintaining the delivery of high quality care. Examples include:

- A University of Southern California study funded by NCHSR found that cervical cancer screening done at four-year intervals, instead of annually, could result in significant annual cost savings and only a slight increase in the numbers of deaths due to the disease. This was one of the first evaluations of the "Pap smear," which costs about $76,000 per incidence detected when done annually, compared to about $18,000 when screening is done every four years.

- A pioneering evaluation supported by the NCHSR found that advanced pre-hospital care roughly doubles the chances of cardiac arrest victims surviving both the trip to the hospital and the hospital stay. Another two-year pilot study found that cardiac arrest patients receiving on-the-scene emergency treatment from emergency medical technicians trained to defibrillate the heart were five times as likely to survive as were patients who received basic resuscitative care.

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- Concerns about the overuse of computed tomography (CT) prompted an NCHSR evaluation of one of the most commonly performed CT studies, cranial computed tomography. Dr. Barbara McNeil, of Boston's Brigham and Women's Hospital, found that cranial CT technology is being used appropriately, and discrimination algorithms could not significantly improve on the preselection of those patients best suited for cranial CT studies. The research also resulted in a new statistical technique that can reduce the number of cranial CT studies requiring "marker dyes" by about 30 percent, thus cutting costs and reducing patients exposure to x-ray radiation.

- Pioneering evaluation was done with NCHSR support of the three most-used breast screening methods--mammography, thermography, and clinical examination--in terms of their specificity and sensitivity, potential radiation hazards, and the extent to which costs would be born by patients. Washington University researchers concluded that risk level--which is determined mostly by age--is the primary consideration for screening asymptomatic women for breast cancer. Findings were published by Praegar Publishers in Early Detection of Breast Cancer Risk,Detection Protocols, and Therapeutic Implications.

- Utilization of the proper selection and implementation strategies suggested by a workbook developed to assist hospital decision makers in the activities related to the acquisition, use, and management of Automated Hospital Information Systems (AHIS) could result in an annual savings of $50 million. Given that the AHIS industry projects billings between $1 and $2 billion a year, use of this workbook may result in a significant savings to hospitals.

- Estimated savings of $30 million, or 20 percent of State expenditures on Cardiac Care Unit (CCU) care (1977 data) could be achieved through tightening CCU admissions and discharge practices. Even greater savings would result if hospitalization for simple acute myocardial infarctions (AMI) were limited to seven days, and selected AMI patients received home treatment.

- A screening protocol that recommends x-rays for patients exhibiting any of 14 clinical indicators has shown a reduction in unnecessary x-rays of limb injuries. Adoption of this protocol could save between $79 and $139 million nationwide without compromising quality of care.

- NCHSR sponsored the first comprehensive literature review of the costs and benefits of electronic fetal monitoring. This controversial study stimulated FDA and industry evaluation of the technique.

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- Cost estimates for reactions known or thought to be associated with six commonly used vaccines were developed by A. D. Little, Inc. The results have important implications for the administration of large-scale immunization programs, such as the national swine flu immunization program of 1976, and for considering options for dealing with liability and compensation for vaccine-related health problems.

- The high mortality rates in some hospitals for cardiac bypass surgery, angiography and cardiac catheterization, total hip replacement and respiratory distress syndrome underscore the potential improvement if more patients could be channeled to high volume institutions. These are difficult conditions and operations, often requiring specialized equipment and highly trained personnel. Understanding this type of variation has important implications for the quality of care.

- A new approach to home health care for the elderly who are homebound and chronically ill has been shown to provide effective, less costly care to the terminally ill. In a randomized, controlled trial, a team consisting of a physician, a geriatric nurse practitioner, and a social worker provided continuous, on-call medical care to patients in their home. Overall costs were about a third less than total costs for patients receiving traditional at-home care, owing to decreased hospitalizations. Satisfaction with care was significantly greater among team care patients and family members.

- Drug education strategies can be very effective both in reducing Medicaid costs and in improving the quality of care. Prescribing behavior was substantially modified by "counter-detail men" for three types of drugs: potentially dangerous analgesics (Propoxyphene), ineffective vasodilators (Papaverine), and expensive antibiotics (Cephalexine). Comparable results were also achieved through physician counseling and education in a study of six classes of drugs, including tetracycline prescribed for children under eight and the use of antipsychotic drugs and Valium in nursing homes.

- Information about the status of each patient's immunizations, tests or other care can help physicians to improve patient care significantly. Indiana University researchers have demonstrated that computerized reminders result in greater compliance with accepted treatment regimens and more frequent use of preventive care measures.

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- The Coronary Artery Disease Databank at Duke University now predicts diagnostic and prognostic results for individual patients better than expert cardiologists. Duke staff are currently using the databank to evaluate various non-invasive procedures as replacements for invasive testing, and are developing and refining statistical methods for determining the information gain or marginal benefit of various medical technologies.

- The American Rheumatism Association Medical Information System (ARAMIS) was developed at Stanford University. This large database has helped to define when the use of renal biopsy is appropriate in the diagnosis of systemic lupus erythematosus and scleroderma. Defining the benefit of specific diagnostic and therapeutic procedures helps to reduce the uncertainty that underlies variations in medical practice.

- In a series of decision analyses concerning the cost effectiveness of alternative strategies in the diagnosis and therapy of 13 common ambulatory care problems, (which together account for between 100 million and 200 million visits per year), a number of cost-saving and quality-enhancing strategies were identified. One illustration is the choice when seeing a patient complaining of a sore throat, between 1) obtaining a throat culture to determine if strep throat is present and then giving penicillin, 2) giving oral penicillin immediately without obtaining a culture, or 3) doing nothing. If the probability of strep throat is 3% or less, (and this includes about 40% of cases) there is no question that the "do nothing" strategy is superior, resulting in fewer deaths and lower costs.

NCHSR - HEALTH PROMOTION AND DISEASE PREVENTION EFFORTS

Question. What contribution has NCHSR made to the Department-wide Health Promotion and Disease Prevention efforts?

Answer. The Center's major activities in health promotion/disease prevention are in its extramural research program. During the past year, the following noteworthy projects have been completed:

- One recently completed monograph examines the potential of preventive medical care for improving health and saving medical expenditures. It describes in detail the policy debates about several important preventive measures--smallpox vaccine, measles vaccine, drug treatment for high blood pressure, and regular exercise. In the context of the examples, the study discusses the methods of cost-effectiveness analysis and, when studies are available, presents the results of these methods. Finally, the author proposes a framework for the design of future studies of

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prevention, suggesting standardization of certain items in cost-effectiveness studies of preventive activities to make a wider range of comparisons possible. Drawing upon the existing body of literature on prevention, the author has identified salient prevention issues and organized them in a non-technical fashion for dissemination to policy makers as well as to scholars.

- Another recently completed study evaluated the effectiveness of primary care physicians in a health maintenance organization (HMO) in providing preventive health services. One part of the investigation used a randomized clinical trial to test several strategies physicians may use to increase patient compliance with colorectal screening. The experimental interventions were (1) a physician talk, (2) a postcard reminder, and (3) a follow-up phone call. Compliance rates were significantly improved by all experimental interventions; the group receiving all three interventions achieved a 94% compliance rate. The postcard reminder was the most effective single intervention, increasing the probability of compliance by 25%. Because of the low cost of this intervention, this finding would suggest that postcard reminders should become a standard adjunct to routine screening requiring patient compliance.

- Another recently completed study evaluated the effect of computer reminders on practice patterns of various medical practitioners. The study found that the computer reminder had a substantial effect on practice particularly on the provision of preventive care. Although a control group of practitioners expressed good intentions with respect to preventative practices, the group receiving the reminders were two to three times as likely to implement those practices.

- This year NCHSR sponsored a conference to develop a research agenda on Iatrogenic Disease and Geriatric Medicine, which was designed to stimulate research and identify additional areas needing research. The Center also published proceedings of a Conference on Disease Prevention and Health Promotion for children and the elderly.

HISPANIC HANES

Question. Why are you decreasing support for the Hispanic National Health and Nutrition Examination Survey by about $1 million?

Answer. Data collection, the most costly phase of the Hispanic Health and Nutrition Examination Survey, was completed in December 1984. The requested level of funding in FY 1986 will cover the costs of processing, editing, and analysis of the data.

Question. When may we expect to see a report on the results of this study?

Answer. The first results will be reported in November, 1985 at the annual meeting of the American Public Health Association to be held in Washington, D.C.

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Question. Can you share any preliminary findings or concerns with the Committee?

Answer. Prior to the release of the data in November 1985, NCHS will be involved in processing, editing, and analysis of the data, and we do not have any preliminary results to present at this time.

SMOKING AND HEALTH BUDGET

Question. You are requesting $3.5 million for the Smoking and Health budget for FY 1986, the same as last year. Please describe your planned program in this area, and are you requesting enough funding to conduct these activities?

Answer. The FY 1986 request of $3.5 million will permit the Office on Smoking and Health to effectively conduct its program of alerting both the general public and health care professionals to the harmful effects of cigarette smoking.

Activities planned for FY 1986 include continuation of the national public information media campaign designed to assist and encourage current smokers to quit and others, particularly female adolescents, not to take up the habit. The provision of scientific and technical information to the research and public health communities will be continued through the Technical Information Center and the issuance of the Surgeon General's Annual Health Consequences Report. In addition to these activities, the Office will continue to monitor, evaluate and analyze changes in smoking trends, attitudes, and behavior for policy and program development.

Finally, the Office will fully implement the provisions contained in the 1984 "Comprehensive Smoking Education Act." The Act calls for the Department to begin monitoring and evaluating cigarette additives; establishes an Interagency Coordinating Committee on Smoking and Health; and requires the development of a biennial comprehensive report to Congress on Federal and private sector activities to inform the public of the health consequences of smoking.

ADOLESCENT FAMILY LIFE

Question. What specific kinds of research projects have been funded and when will these findings be made available to those concerned with making program and policy decisions at the Federal, State and local levels?

Answer. To maximize its contribution, Adolescent Family Life (AFL) research has concentrated its efforts on areas not being addressed by other research programs. These include: the determinants and consequences of premarital adolescent sexual relations; behavior patterns during adolescent pregnancy, especially the decision to keep the baby or make an adoption plan; and the effects of care services on the outcome of pregnancy and the subsequent development of the adolescent and her infant.

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Several research projects are completed and we expect that their findings will shortly be made available to decisionmakers at the Federal, State and local levels through the data archive, and the DHHS human services clearinghouse activity, Project SHARE.

Among the studies completed is one addressing adolescent sexual relations based on a representative sample of parents and their adolescent children, male and female, in Cleveland. It confirms the preliminary findings of other AFL-sponsored studies with respect to the general nature of family interaction on matters related to adolescent sexual behavior. In the typical family, parents and children rarely communicate, and if they do communicate, it is briefly and about the least sensitive topics. When communication occurs it is mostly between mothers and daughters, with father and sons hardly ever being involved. While these findings about present conditions are discouraging, the Cleveland study also produced findings which are encouraging for prevention projects: parents and their children are concerned about each other's views on adolescent sex and want to communicate; once effective communication begins, it is sustained and expanded; where effective communication is established, adolescent girls have a better understanding of their mother's sexual values; and when mothers and their adolescent sons communicate, their sons are more likely to postpone sexual activity.

Another recently completed adoption project was undertaken to learn what counselors know about adoption procedures, how they feel about it as an option for the pregnant adolescent, and what they convey to their clients about it. The study found that counselors believe most pregnant adolescents are not interested in adoption, and because they use the non-directive counseling techniques, counselors rarely initiate discussion of the adoption option. Consequently, adoption is rarely considered as a viable alternative in the counseling of pregnant adolescents.

Other research projects currently being supported include:

- Child Trends, Washington, D.C. This study investigates six factors which might explain why some adolescents initiated sexual activity and some did not. It will include information on the characteristic of family peers, schools, neighborhoods, media, and religion.

- Battelle Memorial Institute, Seattle, Washington. This study examines the short-term effects of sexual behavior or on selected behavioral and attitudinal changes in the adolescent.

- Columbia University, New York, New York. This study examines the extent to which premarital sexual activity is associated with other behavior to form a relatively distinct pattern of adjustment.

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Question. How do you plan to evaluate and disseminate all the information gathered from the AFL's research and demonstration projects?

Answer. Legislation requires an individual evaluation of each project and that all grantees establish working relationships with colleges or universities in their states for the monitoring and evaluation of project services. In addition to these individual evaluation efforts, an evaluation plan is being designed for all current grantees by program staff expert in this area. We expect to report to Congress on this plan by May 1st.

Initial funding for research and demonstration projects was provided in September 1982 and final results of these programs will not be available until the projects are completed. However, we have already initiated a major dissemination activity. We have set up a data archive, where data on adolescent pregnancy and pregnancy prevention are deposited and are made readily available to anyone interested in these issues. When AFL research grants are awarded, we require that public use data tapes be placed in a data archive within 18 months after the end of the study.

Other dissemination efforts that will be utilized include: Project SHARE, the DHHS human services clearinghouse; national organizations and States networks concerned with adolescent pregnancy care and prevention services; and public media resources, such as: professional journals, public forums and meetings, community newspapers, and publications of State and local organizations. Program funds will be used only to facilitate this strategy or to supplement these channels if they prove inadequate to the task.

Question. Are the demonstration projects that were funded in FY 1984 serving minority populations?

Answer. Since its inception the Adolescent Family Life Program has been very involved in providing services to minority adolescents. Twenty-eight of the 71 demonstration projects funded in FY 1984 served clientele in which the proportion of minorities was more than 60 percent.

Question. Will your FY 1986 funding request for demonstration grants--which is less than the amount used for fewer demonstration projects in FY 1985--be adequate to support these projects? Where (what year) in the project cycle is each grant?

Answer. Yes. The budget request of $14.7 million is adequate to support 66 continuations and 5 new model demonstration projects in FY 1986. Title XX requires that grantees provide matching funds of 40% of the total project costs during the first and second year of operations. During the next three years of the project period the level of matching funds from the community increases 10% annually until the projects fifth and final year when Federal support is only 30% of the total cost. Because of this decreasing level of Federal support, funds used for previously funded projects become available for new grants.

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In FY 1985, 22 percent of the continuing AFL demonstrations are in the second year of their project cycle, 15 percent are in the third year, and 63 percent are in their fourth year.

Question. In what areas do you anticipate savings under the proposed rescission of $10,000 for FY 1985 and the withholding of $27,000 for FY 1985?

Answer. Under the proposed FY 1985 rescission, the Adolescent Family Life program will save $10,000 in travel and transportation of persons, transportation of things, and printing. The FY 1985 withholding of $27,000 will save funds which would have supported consultant and related services.

Question. What amount is included in the FY 1985 estimate for the "Standard Level User Charge?" What will be accomplished with these funds?

Answer. In FY 1986, $174,000 is included for the Adolescent Family Life Program's Standard Level User Charge (SLUC). This represents the costs for GSA space assigned to the Adolescent Family Life Program. It includes funds to support the Program's share of rent, utilities, fuel, and maintenance of heating, ventilation, and air conditioning systems.

Questions Submitted by Senator William Proxmire

NATIONAL CENTER FOR HEALTH SERVICES RESEARCH

Dr. Mason, as you know, I chaired a special hearing of this Subcommittee last fall looking at variations in patterns of medical practice and outcome research. One point is clear from that hearing: how little we know about what is actually going on out there in medical practice and in health services delivery. It's equivalent to attempting to drive a $90 billion Medicare and Medicaid truck without investing in windshield wipers to see where we are going.

Now this committee is aware of internal rearrangements of funds within the Department which is depriving the National Center for Health Services Research of the full funds this committee directed you to provide. In my view that's short-sighted and a clear example of being penny-wise and pound-foolish. You know that we will be asked by the administration in the next few years to expand the competitive initiatives that we began with the DRGs. At the same time we are all besieged by constituents who argue that quality of care and access are being sacrificed on the altar of cost containment. So if the administration expects congressional support, we will need the right data to know what is happening out there to assure that our frail elderly are being protected.

Question. I would like you to submit for the record a list of the projects that would have been funded under the NCHSR's original FY 86 budget request that are not covered by the budget request before us.

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Answer. We would have used that money to look at a number of issues, including the development of methodologies for looking at cost-benefit and cost effectiveness of various technologies. We would have been able to support studies that looked in addition at the small area variation question and some studies of effects of prospective payment on the health care delivery system. We are carrying out some of those kinds of activities within our regular appropriation. Since we are speaking here about an investigator-initiated extramural research grant program, it is hard to specify exactly what additional projects might be funded because they have to go through the peer review system.

LIST OF POTENTIAL PROJECTS

Question. I would also like you to submit for the record a listing of the projects that would have been funded in the current fiscal year if you had followed this committee's mandate to expand the Center's funding by $5 million.

Answer. The listing follows:

Policy Conference: Paying Physicians for Geriatric Care
Methods for Exploratory Analysis of Clinical Data Banks
Economics of Planning Cardiovascular Clinical Trials
Consistently High and Low Elderly Users of Medical Care
Evaluation of Quality of Nurse-Midwifery Care
Home Health Care as a Substitute for Hospitalization
Dental Demand and Public Oral Health
Improved CPR Instruction Via Telephone - A Randomized Trial
Analysis of Employer Innovations to Control Health Care Costs
Access to Prenatal Care: Role of Institutional Factors
Ambulatory Care Visits Outside the Private Sector
Hospital Competition, Nursing Wages, and the Cost of Care
Use of Familial Risk in HP/DP in Colorectal Cancer
Response of Providers to Increased Health Care Competition
Non-Biomedical Influences on Clinical Decision Making
Variations in Physician Practice Patterns
Cost Containment in Primary Care
Variations in Ambulatory Care Quality and Service Use
Adverse Selection in Multiple-Option Group Insurance
Severity of Illness in Children: A National Study
Economic and Social Factors in Gastric Bypass Surgery
Service Use and Costs Associated with Kidney Transplantation
Societal Factors in Physician Decision Making
Clinical Efficacy and Cost Effectiveness of MR Imaging
State Rate-Setting: New York Experience
Patterns of Treatment in Long Term Hospitalization

NATIONAL MEDICAL EXPENDITURE SURVEY

Question. Third, I was delighted to see that your budget request prominently mentions a second National Medical Expenditure Survey. The first survey in 1977 has provided us with invaluable information and in fact has provided the rationale for most of the Administration's cost containment initiatives.

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But my concern is the timetable for your second survey. You know that you should have initiated this several years ago. It's similar to the Congress making economic policy with the Bureau of Labor Statistics only collecting data once a decade.

Are you technically capable of letting the first contract that your budget proposal discusses in the current fiscal year rather than in FY 86? And what is the proposed time frame for each of the sequences of this survey? And finally, when can Congress expect the first data results based upon your proposed timetable?

Answer. In recent years there have been major changes in the way medical care is organized and paid for. These changes include modifications in Federal reimbursement policies and the increase in HMOs and multihospital systems. By 1987 we believe it will be possible to obtain information on the consequences of these changes. It was on this basis that the decision was made early in FY 1984 to field the new health care expenditure survey (NMES) in FY 1987.

Having made the decision to field this survey in 1987, it is not now possible to advance the date. It is estimated that roughly $4.0 million might be saved by using the National Health Interview Survey (NHIS) in 1986 to provide the sample for (NMES). To accommodate this approach the 1986 NHIS will be larger than the 1985 survey.

We plan to award the data collection contract early in FY 1986, to draw the sample from the 1986 NHIS, and to pre-test the various questionnaires that will be used.

The time frame for the complete survey is as follows:

May, 1985	Request for clearance forwarded to OMB.
September, 1985	OMB approval obtained.
October, 1985	Announcement that bids for the data collection contract will be accepted.
January, 1986	Data collection contract awarded.
January, 1986-December, 1986	Questionnaires pretested and sample developed.
January, 1987 - April, 1988	Data collection for household and nursing home component.

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May, 1986	Data available for analysis from first 4 months of the household survey.
April, 1988 - February, 1989	Data collection for health insurance, medical provider and physician practice components.
May, 1990	Data files available from contractor.

Based on the experience in 1977, we expect the first findings to be available to Congress in spring, 1988.

NCHSR - MEDICAL EXPENDITURE DATA

Question. Secretary Mason, I want to emphasize the importance that even fiscal conservatives such as myself place on good, solid data so that in our efforts to reform the health care system and improve its efficiency, that we do not kill the goose that lays the golden egg in the process. So I expect that you will take that message back to the Department, Secretary Heckler, your overseers at OMB and anyone else that needs to be consulted and then have your staff work with my staff and this Committee's staff to see whether you can't reconsider your budget priorities within this area, staying--as I know you will--within the President's overall budget targets. Can I expect your cooperation on that?

Answer. I am fully supportive of the efforts to update our information on medical expenditures. We do not have current data on the use of services, patient characteristics or detailed descriptions of insurance coverage. The funds included in the FY 1986 budget will permit us to initiate the planning and design work for a National Medical Expenditure Survey. I am confident that the updated survey will be of significant benefit as we continue to address the significant changes which have occurred in the health care sector.

NCHSR - VARIATIONS IN MEDICAL PRACTICES

Question. As you know, Dr. Marshall, this Subcommittee held a special hearing last November 19 to examine variations in medical practice patterns. The hearing focussed in part on research into the long term outcome of commonly used surgical procedures. Can you tell us if you plan to support any outcome studies of this type next year?

Answer: The National Center for Health Services Research and Health Care Technology Assessment has supported long-term research on variations in medical practice. Analyses of small area data and large data sets have consistently indicated that patient need is not the sole force in how resources are used in health care. Health services research has shown that variation in utilization reflects a complex interaction of clinical, social, environmental, economic and psychological factors which characterize the

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relationship between patient and provider. Studies have consistently demonstrated that differences in medical decision making are often the result of how physicians are trained and of financial incentives in the health care delivery system. Continued empirical analyses of the system are necessary to highlight those medical procedures which could be performed more efficiently or those diseases which could be treated more effectively.

The following are examples of the kinds of research that NCHSR intends to pursue to obtain a better understanding of variations in the use of medical resources and related outcomes:

- o Expanded quality assessment efforts such as studies linking the process of care with outcomes and health status, as well as better ways to measure the effectiveness of the cognitive elements of medical care such as patient-provider communication, and to explore the area of patient and societal preferences or utilities.

- o Sources of data to examine the course of episodes of illnesses over time, including measures of health outcomes which can be obtained unobtrusively.

- o Population-based data for comparative studies of variations in use, particularly with regard to disadvantaged groups, and data which can be used to observe changes in variations over time.

- o Research designs such as cohort or case-control studies which can be carried out in addition to randomized controlled clinical trials in promoting consensus about treatment effectiveness.

NCHSR - RESEARCH ON MEDICAL TECHNOLOGIES

Question. Last year legislation was enacted giving the National Center for Health Services Research the responsibility of supporting research to determine the safety and effectiveness of medical technology and practice. What plans do you have to support research into the effectiveness of existing medical technology and practice in fiscal year 1986? Do your plans include clinical research related to any specific disease areas?

Answer. A grant solicitation has been drafted and deals with appropriate use, effectiveness, cost-effectiveness and societal impacts of health care technologies. It is expected that such research will address a broad spectrum of technologies including drugs, devices, medical and surgical procedures, as well as organizational and supportive systems which contribute to the efficient and cost-effective delivery of health services.

The Center's authorization does not permit support of disease specific clinical research as that is normally the responsibility of the National Institutes of Health. We do, however, support health services in which measures of safety and efficacy as well as variations in utilization may be of significance. (Thus, an assessment of exercise treadmill testing may involve review of the evidence on the safety and efficacy of that diagnostic test in

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Coronary Artery Disease.) Our research would also include studies of the social and economic factors which may influence use of the technology.

PURCHASE OF DRUGS AND MEDICAL SUPPLIES

Question. Dr. Mason, last June your Inspector General came out with a report that was critical of the way in which the Public Health Service purchased commonly used drugs. The report indicated in fiscal 1982 PHS purchased $39 million worth of drugs on the open market although $8.5 million worth could have been purchased through the Defense Personnel Support Center or through the use of the VA's Federal Supply Schedules, saving $3.8 million.

I understand PHS plans to become a partner with DOD and VA in a shared contracting arrangement which would reduce the cost of drug procurement. Can you tell us when the partnership will become operative?

Answer. The shared procurement agreement between PHS, Department of Defense, and the Veterans Administration became effective in June 1984. Items were first offered for sale under the agreement in December 1984.

Question. That same IG report calculated that PHS could save about $1.8 million a year by purchasing generic rather than brand name drugs. Are you implementing any changes in this area?

Answer. Systems are in place which require justification for the use of brand name drugs. The Health Resources and Services Administration, through its Pharmacy and Theraputic Committees, requires physicians who desire to use brand name drugs to justify why they are needed. The Committee then exercises medical judgment in determining if the drug is medically necessary. The National Institutes of Health has established their formularies comprised primarily of generic drugs and has a system for justifying the use of brand name drugs. Both agencies require prescribers to sign a statement when a brand name is considered necessary. Physician prescriptions are reviewed periodically to reveal any unusual prescribing patterns.

Question. While we are on the subject, have you ever considered making the PHS drug formulary, which uses generic names where possible, available to the public? I understand the list is thoroughly screened by 11 PHS Pharmacy and Therapeutic Committees. If the list was made available it might lower drug costs by encouraging the substitution of generic for brand name drugs.

Answer. The drug formularies used in the PHS facilities do commonly list drugs by generic name where possible; however, PHS does not maintain a consolidated drug formulary for common use in all facilities. The formulary for each facility is a custom designed document aimed at the specific patient population of the facility. The unique characteristics of that population such as age, sex, race, geographic region and other morbidity factors determine which drugs are to be included in that particular formulary.

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GRADE CREEP

Question. Dr. Mason, last year the administration made an effort to reduce the number of employees in the higher grades. The Office of the Assistant Secretary for Health (OASH) planned to reduce the average GS grade from 10.25 in 1984 to 10.19 in 1985.

This year's justifications indicate that your average grade actually went up to 10.30 in 1985. Can you tell us why OASH has been unable to achieve its grade reduction goals?

Answer. OASH has been in a relatively static employment situation and the principal change has been attrition which has occurred primarily in the lower grades. As a result, the average grade for OASH as a whole has not been lowered.

Question. I note that your executive service positions, which will cost an average of $68,350 apiece in 1985, jump from 23 last year to 25 in 1985. Can you tell us why your are increasing these slots in the face of a cut in total personnel?

Answer. The change from 23 to 25 employees serving in the Senior Executive Service reflects a conversion of 2 employees from the GS or GM classification to the Senior Executive Service classification. Therefore, there is no net change.

TITLE X ALLOCATION FORMULA

Question. The Committee included language in last year's report directing the Department to again review the family planning allocation formula and report back to the Committee prior to the submission of the 1986 budget request. Why wasn't this report submitted in a timely fashion?

Answer. We apologize for the delay in submitting the report on the allocation formula. We have recently taken actions to ensure that any future Congressional requests for information are provided in a more timely manner.

NIH ROLE IN TECHNOLOGY ASSESSMENT

Question. What role do you see the NIH playing in support of the Center's mission of assessing new and existing technology procedures?

Answer. We see the role of NIH as continuing to fund clinical trials, which we consider one of the fundamental building blocks of health care technology assessment. In addition, we anticipate that much of the longitudinal data on large cohorts of individuals which has been collected for various NIH investigations could be used by NCHSR to evaluate the effectiveness and cost-effectiveness of specific therapeutic interventions.

We also anticipate that the Office of Medical Applications of Research (OMAR) will continue to serve as a liaison between the Center's Office of Health Technology Assessment and the Bureaus, Institutes and Divisions of NIH, so that the benefit of clinical

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knowledge at NIH can be brought to bear on the Medicare coverage recommendation process.

MULTIPLE SCLEROSIS

Question. I understand that multiple sclerosis is a disease being treated with a number of existing and new therapies whose value is either highly questionable or, as yet, undetermined. Some of these therapies are also being applied to related diseases and are costing the Medicare and Medicaid programs a considerable amount of money. Does the Center believe that research into such questionable therapies is within its mission under the 1984 amendments?

Answer. Multiple sclerosis is a chronic disease of unknown cause for which there is no established means of proving the diagnosis during life. Its variable and unpredictable course is characterized by steady progression, stabilization, episodes of exacerbation and remission, and therefore it represents a good example of the kind of illness about which health services research and technology assessment efforts can contribute important information concerning diagnostic and therapeutic as well as economic and social issues.

In the area of diagnosis, for example, the field of health services research includes studies of the information gain and the cost-effectiveness of new diagnostic technologies, such as Magnetic Resonance Imaging or Positron Emission Tomography, as well as the development of methods to assess and compare severity of illness. An extraordinary variety of treatments have been suggested for diseases like multiple sclerosis, ranging from snake venom to lettuce diets; this agency has completed assessments of two technologies recently proposed for treating multiple sclerosis - hyperbaric oxygen therapy and apheresis - and has determined that the published results do not support claims of effectiveness.

Because the course of chronic diseases such as multiple sclerosis is highly variable, the effects of different treatments cannot properly be determined by anecdotal information or case studies. Health services research has led to the design and development of disease registries - "data banks" - which have been shown to be particularly useful in evaluating the results of different regimens for managing such illnesses. Furthermore, several investigators in this field have succeeded in constructing and validating a number of health status indexes and measures of functional disability which are essential for assessing the immediate and long-term results of treatment. Other ways in which health services research can provide additional information for continuing discussion of these issues include studies of the effect of different system configurations or reimbursement methods on treatment practices, variations in the types and the quality of care given by different types of health care providers, and assessment of the social and economic effects of these diseases on families, communities, and public agencies.

NCHSR STAFFING

Question. Last year you requested and we provided funding for 102 positions for Health Services Research program operations.

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This year's justifications indicate that you have allocated 118 positions to program operations, 16 more than we provided for. Can you tell us what brought about this change?

Answer. First, it is important to note that the 102 reflected budgeted positions and the 118 represents full-time equivalents which include calculated work-years for all employees--those which occupy budgeted positions and those which are part-time or temporary and do not occupy budgeted positions.

The 1986 justification reflects a change in the way the staffing is displayed, and is not a staffing increase. In fact, the National Center for Health Services Research and Health Care Technology Assessment (NHCSR/HCTA) has had a significant reduction in staffing over the past several years, as reflected on the following comparable table:

NCHSR/HCTA Staffing

	Program Operations		Program Support		Total	
	Pos.	FTE	Pos.	FTE	Pos.	FTE
1981	183	207	31	34	214	241
1982	108	134	31	34	139	168
1983	109	123	30	31	139	154
1984	114	128	30	30	144	158
1985	109 1/	118	30 1/	30	139	148
1986	102	111	30	30	132	141

1/ The 1985 budget justification shows 102 positions in program operations and 37 positions in program support. However, eliminating unnecessary administrative management practices and improvements in program accountability have permitted the assignment of 7 Program Support positions to the Program Operations activity.

EQUIPMENT INCREASE

Question. I notice that your equipment budget is scheduled to increase from $670,000 this year to $2,607,000 in fiscal year 1986. Can you tell us why you require an increase of this magnitude?

Answer. The FY 1986 budget for the Office of the Assistant Secretary for Health requests $2,607,000 for equipment, an increase of $1,937,000 over the 1985 level of $670,000. The majority of this increase is related to the National Health and Nutrition Examination Survey (NHANES). Funds will be used for the purchase and renovation of mobile examination centers and the purchase of diagnostic equipment used in conducting the survey. In addition, a portion of the funds will be used to purchase

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necessary equipment to automate data collection for the survey programs of the National Center for Health Statistics (NCHS). By converting many of the existing manual methods for collection and preparation of data to electronic form, NCHS can reduce the time between the collection and release of data and make the Center's data systems more responsive to current public health issues.

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Questions Submitted by Senator Lawton Chiles

INFANT MORTALITY

Question. Since 1965, infant mortality in this country has been reduced by 50 percent. Yet we are still 12th among the developed nations of the world in the chances of a newborn baby surviving its first year. The reduction in infant mortality we have seen in the past twenty years has been almost wholly due to technological advances. That is leveling off now, as far as how far we can go in saving high risk, low birth weight babies. What is not declining is the incidence of low birth weight infants.

The Institute of Medicine has released a report that suggests that it would cost less to prevent low birth weight, through nutrition and prenatal care, than for all the high tech neonatal care. Yet your budget does not even provide inflation increases for the programs that provide nutrition and prenatal care aimed at the highest risk population -- the women on welfare ages 15 to 39 with less than 12 years of education.

How do you justify this?

Answer. The $478 million request for FY 1986 is the same level as FY 1985. However, the budget request provides that $418 million be distributed to States under the block grant authority as compared with $406 million in FY 1985. This is accomplished by reducing support for special project grants to the FY 1984 level and

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increasing the allocation which States may use in their service delivery activities. States will therefore experience an increase in the funds available to them for MCH service programs in FY 1986. This increase will assist them in meeting the cost of inflation. Additionally, States will provide another $9 million in FY 1986 to fulfill their matching share requirements under the MCH block grant law.

Question. Have you "costed-out" or analyzed what the cuts since 1980 in Maternal and Child Health and Primary Care and Family Planning have meant in terms of low birth weight and infant mortality?

Answer. As the following reflects, overall Federal budgets for these programs have been decreased in one of the last six years:

In Millions

FY	Primary Care (Includes Migrant Health	Title X FP	Title V	Federal Subtotal	State Match (Title V)	Total Available
1980	360	162	376	898	163	1,061
1981	357	162	387	916	170	1,086
1982	319	124	374	817	238	1,055
1983	333*	124	373*	830	237	1,067
1984	379	140	399	918	254	1,172
1985	419	143	478	1,040	305	1,345

*NOTE: The Jobs Bill Supplemental appropriation provided $65 million to the CHC, and $105 million to the MCH appropriations in addition to the amounts shown. The MCH, CHC and FP 1983 subtotal including the Jobs Bill Supplemental is, therefore, $1,000 million.

It would be very difficult to determine what effect the availability of Federal funds for these programs has had on low birthweight and infant mortality. While there is no doubt that these funds impact significantly on the provision of preventive and prenatal services for high-risk women, there are many other variables which affect rates, e.g., socio-economic conditions utilization of care, health and health related habits of mothers, etc.

Question. In the programs you administer, is there any kind of coordinated attention and strategy for preventing infant mortality?

Answer. Yes, there is extensive coordination. I would like to submit for the record a recent report from the Division of Maternal and Child Health which summarizes our efforts in this area.

[The information follows:]

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EFFECTIVE PREGNANCY AND INFANT CARE

AN INITIATIVE TO REDUCE INFANT MORTALITY IN THE UNITED STATES

Division of Maternal and Child Health
Bureau of Health Care Delivery and Assistance
Health Resources and Services Administration
United States Public Health Service
Department of Health and Human Services

December 1984

INTRODUCTION

Our system of shared responsibility has contributed greatly to significant achievements in child health in the U.S. However, not all of our children have benefited equally in our progress as there remain distressing geographical variations and disparities between sub-populations in our nation.

Ensuring a healthy start in life for all infants and enhancing the health of their mothers are important components of our 1990 Objectives for improving the health of Americans. The quantitative objectives selected for the Pregnancy and Infant Health area focus on lowering infant, neonatal and perinatal mortality rates, reducing low birth weight, and improving health for pregnant women and infants. Reducing infant mortality and preventing low birth weight are complex problems not susceptible to a simple or quick solution. Moreover, they are national problems that require the efforts of many segments of our society for solution. While it is the responsibility of the individual woman to seek proper medical care and comply with medical advice, responsibility lies with the local community for the provision of support services, the health care professionals to provide appropriate scientifically based advice and care, and the State authorities to define areas of need, plan to meet those needs and help develop the regional systems of care, employing such resources as the health block grants and State and local funds. Over the years, numerous efforts by both the public and private sectors have been directed successfully toward the resolution of many maternal and infant health problems. We can take great pride in our accomplishments; however, our work is not yet completed.

PROBLEM

There are approximately 32 million women of reproductive age in this country. Of these, an estimated six million will become pregnant and 3.6 million will give birth to live infants each year. Included in the birth cohort are several at-risk groups:

- nearly 200,000 babies born to school-age adolescents under 18 years of age, including nearly 10,000 to girls under the age of 15;
- nearly a quarter of a million infants who weigh less than 2500 grams at birth;
- over 900,000 infants born to women who smoked during pregnancy; and
- over one million infants born to women who drank during pregnancy.

Almost 40,000 live-born infants are dying before reaching their first birthdays.

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Infant mortality is defined as the death of a live-born infant under one year of age and is usually expressed as a rate per 1000 live births (IMR). Infant mortality rates in this country have been declining at a rapid pace since the late 1960s as shown on Figure 1. The provisional rate of 10.9 infant deaths per 1000 live births in 1983 is the lowest annual rate thus far recorded for our Nation. Most recently, however, the latest U.S. provisional data indicate a slowdown in the rate of decline of infant mortality. Provisional and final IMRs since 1970 are presented in Table 1. These data indicate that:

- the provisional IMR for 1983 declined by only 2.7 percent from the provisional 1982 rate, well below the annual average decline of 4.6 percent for the previous decade, and the second lowest decline since 1971.

- the provisional IMR for January-November 1984 was 10.6 infant deaths per 1000 live births; only 1.9 percent below the rate for the comparable period in 1983.

These successively small declines are indicative of a slowdown in the infant mortality decline that we have not experienced since the plateau in infant mortality between 1955 and 1965. It is not possible at this time to accurately predict whether this trend will continue.

Partitioning data from selected States by age-at-death suggests that neonatal mortality continues to decline while postneonatal mortality has increased. Postneonatal mortality has been regarded as most susceptible to preventative efforts and a rise in this mortality rate is a serious concern.

Examining the national data further, one finds that the IMR among black infants remains almost twice that of white infants (Table 2). In 1982, the latest year for which race-specific data are currently available, the national IMR was 11.5 per 1,000 live births. The IMR for white infants, however, was only 10.1, while it was 19.6 for black infants. These rates represent IMR declines from 1981 of 3.8 percent for white and 2.0 percent for black infants. The continuing high black IMR is a major concern. This problem, however, is not of recent origin. It has been with us for many decades.

Between 1965 and 1982 the decline in the neonatal mortality rate has been greater for whites than blacks; the white neonatal mortality rate declined by an average of 5.3 percent per year for this period while the black rate declined by an average of 4.3 percent per year. The postneonatal mortality rate, however, declined more rapidly for blacks during this period than for whites; the black postneonatal mortality rate declined by an average of 4.5 percent per year for this period while the white rate declined by an average of 2.3 percent per year. It should be noted, however, that postneonatal rate did not decline for blacks between 1981 and 1982. This is not necessarily predictive of an untoward trend since the 1981 decline in the black postneonatal mortality rate was 10 percent below the 1980 rate and the largest yearly decline since 1965. In addition, there have been several years since 1965 to the present where there was no yearly decline for either black or white postneonatal mortalty rates. The net effect of the differential declines in the age-at-death mortality rates for whites and blacks on the overall decline in infant mortality between 1965 and 1982 was nearly equal for both whites and blacks; an average of 4.5 percent per year decline for whites and 4.4 percent per year decline for blacks for this period.

Low birth weight (less than 2500 grams) is the most important risk factor associated with infant mortality. Compared to the decline in infant mortality, the incidence of LBW has declined relatively slowly during the 1970s and has remained static since 1980 (Figure 2). Blacks continue to be twice as likely as whites to deliver a low birth weight infant (Table 3). Even when several factors are controlled simultaneously, black women continue to be twice as likely as white women to have low birth weight infants.

The relative effectiveness of various interventions to improve pregnancy outcome and infant health is important to consider. The provision of prenatal care of good quality is an important intervention opportunity. There is little question as to the value of prenatal care in contributing to the health of pregnant women and preventing or reducing the complications of pregnancy and

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labor such as eclampsia. It has been asserted that more prenatal care for high risk women will also reduce LBW, however, the task of determining the effectiveness of prenatal care for improving fetal health and reducing low birth weight has been difficult. Recent studies suggest that the quality and content of prenatal care may be the most important ingredients. Yet, despite our increased understanding of risk factors, such as smoking, we still know comparatively little about how to modify at-risk behavior. We need to expand our knowledge in order to target our resources and develop effective responses to prevent low weight births.

The ten years between 1969 and 1979 showed a significant trend toward achieving high rates of early entry into prenatal care and steady progress toward narrowing the black/white gap in receipt of early care. Recent natality data, however, reflect a departure from the upward trend of the previous decade. It is noted that the proportion of mothers who began prenatal care in the first trimester of pregnancy plateaued in 1979 and declined for the first time in 1981 and 1982. Only 61 percent of black women delivering in 1982 received prenatal care in the first trimester compared to 79 percent of white women, and the proportions of both white and black mothers receiving delayed or no care increased between 1981 and 1982.

Additional issues and problems include:

- the inability to identify a "single" factor to account for the differences in birthweight among and between subpopulations
- the "excess" mortality among infants weighing more than 2500 grams at birth
- the infant deaths related to congenital anomalies
- the postneonatal deaths attributable to SIDS
- the system and financial barriers to obtaining early and continuous prenatal care, delivery care and high risk care for mother and baby
- the unhealthy lifestyles among many women of reproductive age
- the inadequate information and expertise about the development and use of data and/or surveillance systems
- the disincentives for breastfeeding
- the availability and access to continuous and comprehensive care for mothers and infants in the early postpartum period and the postneonatal period

BACKGROUND

Communities across this land vary widely in their needs and resources. For that reason, a diversity of approaches, organizational schemes and systems have been developed to respond to maternal and infant health concerns. Most pregnant women and infants in this country receive care from the private sector whether financed by private insurers, Medicaid or self-pay. States, utilizing the Maternal and Child Health Services Block Grant resources, focus on system capacity building and provide an array of services to pregnant women and infants in need of care, especially low income women and children. Additionally, Federal programs sponsored by the Bureau of Health Care Delivery and Assistance (BHCDA) address the underserved at a local level through Community Health Centers (CHC), Migrant Health Projects and through placement of National Health Service Corps (NHSC) health professionals in health manpower shortage areas. A variety of resources support the care of women and infants served by such State and Federal programs; however, a major concern is the identification of funds for needed comprehensive services, including financing for inpatient care.

Achieving optimal health for pregnant women and infants from birth through the first year of life requires the sharing of responsibility by private

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practitioners, hospitals, voluntary organizations, and private and public agencies. Effective and efficient use of resources in our pluralistic health care delivery model necessitates a coordinated, comprehensive and systematic approach to the delivery of maternal and infant health care and generally includes the following:

- o a multidisciplinary approach
- o a family-centered philosophy
- o emphasis on preventive measures
- o outreach and casefinding
- o diagnosis and treatment of health problems
- o risk assessment
- o screening for genetic defects
- o patient education and counseling
- o risk appropriate levels of care for ambulatory and inpatient services
- o linkages for coordination of delivery care
- o linkages for consultation and referral
- o emergency maternal and infant services and transport
- o education about parenting and the physical and emotional needs of infants
- o continuing primary infant care, including preventive measures such as immunization, injury prevention and anticipatory guidance
- o therapeutic and rehabilitative speciality services for acutely and chronically ill infants
- o tracking systems for mothers and infants
- o updating the skills of health care providers
- o suitable financial support for all necessary care and services

This approach forms the basis of regionalized systems of perinatal services which have been promoted since the early 1970s. These systems are networks coordinating multilevel professional services and institutional resources (in a variety of settings and organizational frameworks) to match the intensity of health care to the pregnant woman's and infant's degree of risk. Although there is a tendency in this system to focus on the tertiary unit and high risk care, the core of the system is the delivery of primary care to women and infants. To be effective and efficient therefore, the lines of communication, referral and coordination must be bidirectional, flowing from lower to higher levels and from higher to lower levels. Any system of care must insure that all women are aware of the importance of care for themselves and their children, that all women and infants have care available, and that they avail themselves of it early in pregnancy and throughout infancy. Continuous monitoring of access to care, content of care, and health outcome measures must be in place to assure efficacious service delivery.

The PHS has many activities and programs intended to reduce infant mortality, all of which have been important in the progress we have made in the last 15 years. The following examples highlight some of the current activities:

Service Programs

- o The Maternal and Child Health (MCH) Services Block Grant authorizes annual appropriations for allocation to 57 eligible jurisdictions and provides each State the authority to allocate resources based upon its own needs assessments and priorities in order to assure access to maternal health services of good quality and to reduce infant mortality - especially by providing prenatal care and preventive services. In addition, the MCH program supports a wide range of activities to strengthen the capacity of the States to improve health status outcomes for mothers and children including the awarding of grants for special projects of regional and national significance.

- o The National Health Service Corps (NHSC) and the MCH program are working jointly to identify obstetric and pediatric underserved areas in the U.S. to place about 100 obstetricians and 200 pediatricians to provide direct services in underserved at-risk areas.

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- Community Health Centers (CHC) and Migrant Health projects provide prenatal care to medically underserved pregnant women and are implementing a perinatal initiative to ensure delivery of high quality maternal and infant health services.

- The Indian Health Service, working with tribal health departments, private practitioners and national professional organizations, provides comprehensive maternal and child health services. Emphasis is on early identification of pregnant women and entrance to care, especially for the teenage population, to permit delivery of proper services and early health education.

- Through the Adolescent Family Life Program projects are funded to prevent adolescent pregnancy by reaching adolescents before they become sexually active, to discourage adolescent sexual activity, and to minimize the adverse consequences for pregnant adolescents and their children.

Research Activities

- The National Institute of Child Health and Human Development (NICHD) has assigned the highest priority to research on the low birth weight of infants, the etiology of such births and treatment of affected infants. NICHD, also, has developed an expanded research initiative to prevent low birth weight. The initiative includes research on intrauterine growth retardation (fetal growth factors, biological predictors of fetal growth and Perinatal Emphasis Research Centers); research on premature labor (biochemistry of labor and premature rupture of membranes); and research on environmental factors (nutritional, socioeconomic, risk-taking behavior, physical activity, and working conditions). The initiative includes a cooperative network of maternal-fetal medicine units, centers focusing on perinatal pharmocology and toxicology, and a network of neonatal intensive care units for clinical studies, educational efforts, joint efforts with other agencies and foundations and a low birth weight advisory committee.

- The National Institute on Alcohol Abuse and Alcoholism supports multiple fetal alcohol research projects to address such issues as the effects of binge or episodic drinking, the effects of alcohol exposure during critical periods of fetal development, mechanisms causing the adverse effects of alcohol on infants, and long-range development of children born to mothers who drank during pregnancy.

- In addition CDC, NICHD, DMCH and NCHS support a full range of intramural/extramural research activities related to maternal and infant morbidity and mortality too extensive to identify in this material.

Data and Surveillance

- The CDC, DMCH, and NICHD provide epidemiologic and analytic assistance at the request of States and local health authorities regarding specific maternal and infant health issues and programatic concerns.

- The Centers for Disease Control initiated a National Infant Mortality Surveillance jointly sponsored by NCHS, NICHD and DMCH which will provide birth weight-specific mortality rates for States by various specific maternal characteristics. Such rates and data have not been systematically assembled since 1960. A national conference considering the implications of these data for State efforts is planned for Fall 1985.

- The National Center for Health Statistics (NCHS) is undertaking a study to assess the feasibility of establishing a national system of

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linked birth and death records which will provide an improved data base for monitoring infant mortality trends.

- NCHS and DHCH are working together to link the 1980 and 1981 National Death Index with the 1980 National Natality Survey (NNS) in order to prepare special analyses on infant mortality not available from vital statistics using data such as birth weight-specific mortality rates correlated with maternal complications of pregnancy, and maternal smoking.

- Further, NCHS has established an International Collaborative Effort to identify what we can learn from our international neighbors, especially those countries with the lowest infant mortality rates.

Public and Professional Education

- The PHS was one of the six founders of the Healthy Mothers, Healthy Babies Coalition, a group representing voluntary, health professional and State, local and Federal governmental agencies concerned about the health of mothers and babies.

- The PHS is currently assisting regions across the nation to develop conferences to promote the understanding of the scope, intensity, and significance of infant health issues within their States and communities.

This description of PHS activities constitutes only a partial list of the ongoing efforts. A complete listing is available in the Inventory of Department of Health and Human Services Activities Concerned with Infant Mortality and Lo. Birthweight, Office of the Assistant Secretary for Health/ Planning and Evaluation.

Public attention has become increasingly focused on the problems of infant mortality, low birth weight and delivery of prenatal care. The Public Advocates representing various health and minority organizations, filed a petition with the DHHS in the Fall of 1983 to effect program and policy changes aimed at reducing infant mortality. Subsequently, reports issued by the Children's Defense Fund and the Food Research and Action Center posited a deterioration in child health and emphasized a presumed widening of the gap between mortality rates for white and black infants. On March 16, 1984 Congressman Waxman and Congressman Dingell held a joint hearing on Infant Mortality for the Committee on Energy and Commerce. At this hearing, the position of the PHS underscored the States' responsibilities under the block grants to initiate programs geared to their own needs recognizing the complex nature of these issues, and the need for multiple approaches. During the spring and fall of 1984, the Carter Center of Emory University in Atlanta, Georgia developed a report on the "gaps" in health status, one specific focus being the black/white difference in IMR. In addition, the National Academy of Sciences, Institute of Medicine spent a year studying and preparing a report on the Prevention of Low Birth Weight due to be released in January 1985.

Recognizing the proliferation of the activities directed toward LBW prevention and infant mortality reduction supported by the PHS and by State and local governments and private organizations, the PHS established the Low Birthweight Prevention Work Group in March of 1984. The work group, which reports to the Assistant Secretary for Health, is comprised of representatives of key PHS organizational components which have maternal and child health responsibilities, i.e., DMCH, NICHD, NCHS and CDC. The mission of the group is to formulate and articulate a cohesive PHS strategy including policy and program options for reducing the number of low weight births and the rate of infant mortality in the U.S. The group chaired by the Director of the Division of Maternal and Child Health and the Co-Chairman is the Director of the National Institute of Child Health and Human Development. The work group has coordinated with and contributed to the work of the Infant Mortality Subcommittee of the Secretary's Black and Minority Health Task Force. This work group has assembled maternal and child health experts from the PHS and has served as an immediate source of expert scientific and policy advice for the ASH on matters relating to infant mortality and low birth rate. The

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meetings have facilitated communication between agencies resulting in strengthening and coordinating programmatic efforts. The work group continues to serve these functions as well as to develop long term strategy.

EFFECTIVE PREGNANCY AND INFANT CARE INITIATIVE

Responding to the continued concern for improving maternal and infant health, the Bureau of Health Care Delivery and Assistance (BHCDA) is engaged in seeking improved ways to address this pressing national priority.

Challenges for improving maternal and infant health and reducing mortality rates exist in all States and many may be related to gaps in knowledge or gaps in resources; however, based upon current knowledge and techniques, steps can be taken which are likely to work toward reducing the high rates of infant mortality and excessive numbers of low weight births. The Bureau of Health Care Delivery and Assistance has initiated a multidimensional program to promote Effective Pregnancy and Infant Care (EPIC) within the framework of the 1990 Objectives for the Nation for Pregnancy and Infant Health and the PHS Low Birth Weight (LBW) Prevention Work Group activities. The EPIC program is primarily intended to make assistance available to States in a variety of ways to strengthen structure, continuity and quality of services. The purpose of this support is to improve the manner, scope and effectiveness of health care delivery through resources now available or becoming available.

Through the EPIC program, for example, the Division of Maternal and Child Health will provide professional and technical assistance, e.g., helping to assemble and support teams of experts who can help in the area of infant mortality reviews, develop guidance material on financing of maternal and infant care. The Division of Primary Care Services will encourage CHCs via guidance materials and otherwise to improve the quality of their maternal and infant care. The NHSC will assign obstetrician-gynecologists and pediatricians to underserved areas. BHCDA intends to assist States in developing maternal and infant care systems which integrate primary care services, such as CHCs, and NHSC resources with State MCH programs and local health department resources.

The Division of Maternal and Child Health's general approaches within EPIC are two-fold:

- o working with State MCH Programs to achieve the goals of this Initiative
- o awarding grants within the public and private sectors for special projects of regional and national significance (SPRANS grants) which will ultimately contribute to and strengthen State-wide maternal and infant health care and systems.

An example of a grant which has been awarded is one made to the Southern Governors' Association to aid involved States in assessment of needs, problem identification and implementation of pertinent programs. Specific activities of DMCHs EPIC initiative will focus on three main areas:

- o Improving services and the care delivery system through:
  - demonstrations to assist States and localities in improving the health status of mothers and infants by defining and implementing strategies to address gaps in maternal and infant care systems, especially in those areas with populations having excessively high infant mortality and morbidity and/or those with underserved populations
  - provision of professional consultation to carry out infant mortality reviews and assist with improving and enhancing State and community systems within areas with high infant mortality rates or large underserved populations
  - development and maintenance of networks among States to widen their information bases, coordinate programs, and assist with implementation of programs to reduce infant mortality

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- development of technical assistance materials for States and communities for improving the financing of maternal and infant health services

- demonstrations of models of support for breastfeeding as an integral component of family-centered post-discharge mother/newborn care

- development and implementation of effective strategies to facilitate breastfeeding, especially for working women, including low-income and minority women

- demonstrations of innovative mechanisms to increase access to genetic services and utilization rates by subpopulations at high risk for genetic disease whose members are currently underserved due to language and/or cultural barriers

- development of a capacity to identify and provide appropriate genetic counseling to couples at risk for genetic disorders following repeated fetal losses

- development of a computerized information database of potential teratogens which can be readily accessed by health professionals

- development of state-wide early intervention programs, including appropriate health and education services, for at-risk low birthweight infants and disabled children in the first three years of life

- use of common data elements, data sets and establishment of state-wide data bases for referral and monitoring of services for low birthweight infants

- development of technical assistance materials for States and communities for improving the identification of infants at risk and comprehensive services including health, mental health and educational components

o Enhancing the expertise of health professionals through:

- development of continuing education programs to address the needs in State based programs, advances in technology, and need for improvement in identification, stabilization and referral of sick newborns.

o Developing new knowledge through the promotion of research to:

- examine behavioral aspects surrounding receipt and delivery of prenatal care, e.g., motivation for seeking prenatal care, effect of interaction between client and provider, factors associated with decision making in clinical management

- determine why intervention programs are not effective for all clients

- determine the optimal content of prenatal care

- evaluate population-based preterm labor prevention programs

- examine the impact of current and proposed financing mechanisms on the delivery of maternal and infant health services and health status outcomes

- study infants with regulatory, attachment and motor difficulties in the first year of life and development and evaluation of services for these infants

- develop criteria for identification of low birthweight infants at high risk for chronic illness or disabling conditions and

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establishing appropriate interventions and standards of care for these infants

- develop new screening and diagnostic techniques incorporating family factors to identify those infants at greatest risk for infant morbidity, especially small-for-gestational age infants

- evaluate perinatal projects focused on casefinding, outreach, and/or coordination.

SUMMARY

Because of the decline in the rates of reduction of infant mortality and low weight births as well as the racial disparity in infant mortality and low birth weight rates, professional and public attention in these areas are expected to continue at a high level of intensity. It is our belief that the activities and initiative described in the foregoing will result in meaningful progress with respect to these serious and complicated problems. Our hope is that the totality of assistance will be of significant value in reducing high infant mortality and low birth weight rates.

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Figure 1.

INFANT MORTALITY RATES
1950-83

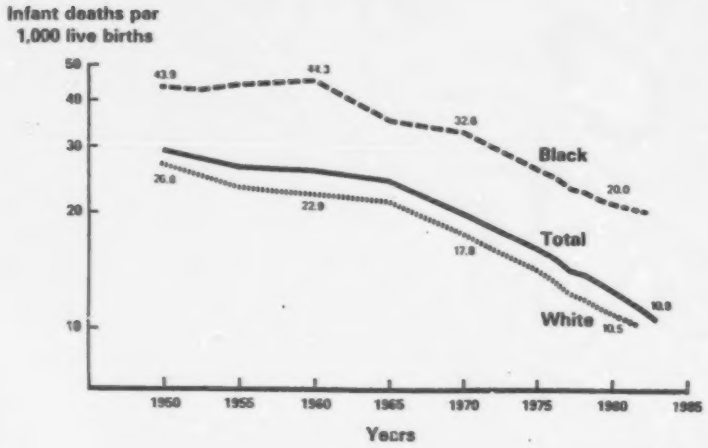

Figure 2.

LOW BIRTH WEIGHT RATIOS
1970-82

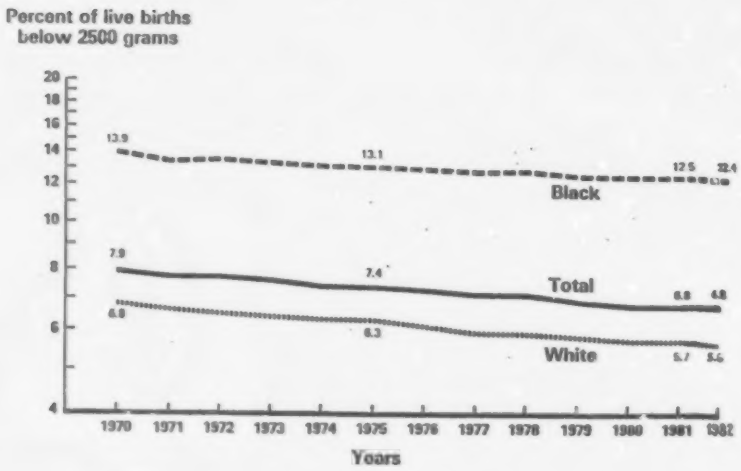

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Table 1. Provisional and final infant mortality rates per 1,000 live births, U.S. 1970-84

	Final		Provisional*	
	Rate	% decrease from previous year	Rate	% decrease from previous year
1970	20.0	-	19.8	-
1971	19.1	4.5	19.2	3.0
1972	18.5	3.1	18.5	3.6
1973	17.7	4.3	17.6	4.9
1974	16.7	5.6	16.5	6.3
1975	16.1	3.6	16.1	2.4
1976	15.2	5.6	15.1	6.2
1977	14.1	7.2	14.0	7.3
1978	13.8	2.1	13.6	2.9
1979	13.1	5.1	13.0	4.4
1980	12.6	3.8	12.5	3.9
1981	11.9	5.6	11.7	6.4
1982	11.5	3.4	11.2	4.3
1983	NA		10.9	2.7
Jan-Nov 1983	NA		10.8	-
Jan-Nov 1984	NA		10.6	1.9

*Provisional based on published rate in December Monthly Vital Statistics Report.

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Table 2. Infant mortality rates by race and ratio of rates for black infants to rates for white infants: United States, 1960-1983

[Rates per 1,000 live births in specified group. Beginning 1970 excludes data for nonresidents of the United States]

Year	Rate				Ratio Black/White
	All races	White	All other		
			Total	Black	
1983[1]	10.9	—	—	—	—
1982	11.5	10.1	17.3	19.6	1.94
1981	11.9	10.5	17.8	20.0	1.90
1980	12.6	11.0	19.1	21.4	1.94
1979	13.1	11.4	19.8	21.8	1.91
1978	13.8	12.0	21.1	23.1	1.92
1977	14.1	12.3	21.7	23.6	1.91
1976	15.2	13.3	23.5	25.5	1.91
1975	16.1	14.2	24.2	26.2	1.84
1974	16.7	14.8	24.9	26.8	1.81
1973	17.7	15.8	26.2	28.1	1.77
1972[3]	18.5	16.4	27.7	29.6	1.80
1971	19.1	17.1	28.5	30.3	1.77
1970	20.0	17.8	30.9	32.6	1.83
1969	20.9	18.4	32.9	34.8	1.89
1968	21.8	19.2	34.5	36.2	1.88
1967	22.4	19.7	35.9	37.5	1.90
1966	23.7	20.6	38.8	40.2	1.95
1965	24.7	21.5	40.3	41.7	1.93
1964	24.8	21.6	41.1	42.3	1.95
1963[4]	25.2	22.2	41.5	42.8	1.92
1962[4]	25.3	22.3	41.4	42.6	1.91
1961	25.3	22.4	40.7	41.8	1.86
1960	26.0	22.9	43.2	44.3	1.93

[1]Provisional.
[2]Figures are subject to change. These are preliminary figures based on a special interim tabulation of data from the 1981 mortality file.
[3]Based on a 50-percent sample of deaths.
[4]Figures by race exclude data for residents of New Jersey because this State did not require reporting of the item for these years.

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Table 3. Percent of infants of low birth weight by race and ratio of percent for black infants to percent for white infants: United States, 1950-82

Year	All races	White	All other races		Ratio Black/ White
			Total	Black	
1982	6.8	5.6	11.2	12.4	2.21
1981	6.8	5.7	11.4	12.5	2.19
1980	6.8	5.7	11.5	12.5	2.19
1979	6.9	5.8	11.6	12.6	2.17
1978	7.1	5.9	11.9	12.9	2.19
1977	7.1	5.9	11.9	12.8	2.17
1976	7.3	6.1	12.1	13.0	2.13
1975	7.4	6.3	12.2	13.1	2.08
1974	7.4	6.3	12.4	13.1	2.08
1973	7.6	6.4	12.5	13.3	2.08
1972	7.7	6.5	12.9	13.6	2.09
1971	7.7	6.6	12.7	13.4	2.03
1970	7.9	6.8	13.3	13.9	2.04

Question. I applaud your request for an increase for the National Center for Health Statistics to conduct an intensive investigation of infant death and birth records to identify risk correlates.

Shouldn't we match this with funding priorities on the programs that we know reduce the risk -- MCH, teen pregnancy prevention, smoking cessation, primary care, etc.?

Answer. In the MCH and Primary Care programs emphasis continues to be placed on reduction of the rates of infant mortality and low weight births. In FY 1986, States will be provided additional funds under MCH and will be given the opportunity to implement the Primary Care Block Grant which would afford them a new flexibility to utilize funds to address their individual needs in the areas of low birth weight and infant mortality and the kinds of preventive services which have been proven to reduce their incidence. The FY 1986 budget places emphasis on the management of Federal assistance through block grants in conjunction with State and local resources by the health authorities in the States themselves. Such authorities are acutely aware of the problems associated with caring for their populations and can most ably apply the resources available. From the Federal level, we are providing the latest infant mortality trend data to States, we are helping disseminate recent reports of infant mortality and low weight births, we are organizing expert teams to assist States in carrying out infant mortality reviews, we are giving priority to improvement in State perinatal systems through MCH project grants and we have proposed the allocation of more funds to the States by reducing the Federal set-aside.

Question. The Administration wants to eliminate all the health professions training and student aid programs. Given the maldistribution and over-specialization we are seeing in health

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care, where are the gaps going to be filled in encouraging professionals to enter family practice, training doctors and nurses to treat the fastest growing segment of the population -- the elderly, and promoting advanced nurse training and research that is so cost-effective in increasing the quality and availability of care?

Answer. In the context of overall aggregate national shortages in the health professions and nursing, we have no shortages. There still remain some particular specialties in some fields that are in short supply. There are also some geographic areas without an adequate number of health professionals. However, it is believed that since the overall supply of health professionals is increasing and will continue to increase for many years, this will help to alleviate those problems.

Question. We see every day the advance of some high tech medical breakthrough that brings us closer to the "bionic" age in medicine. We also see the results of health promotion and life style changes to improve health.

My concern is that we are not making similar progress in bringing very basic health and nutrition education services to the large segment of the population that gets only crisis intervention in the emergency room, and that we are not training adequate numbers of physician assistants, nurse practitioners and midwives and others who can dispense quality care without high tech heroics.

How do the budget requests for your programs address these critical needs in our nation's health care?

Answer. Nearly 20 years ago, the Federal Government began subsidizing health professions training programs on the premise that a financial stimulus was needed because of personnel shortages. The era of gross overall national shortage of personnel is over and special Federal aid programs should come to an end as well. Although there may be some specialty shortages of physicians and nurses in particular areas of the country, the nation as a whole is facing a future surplus -- not shortage -- of physicians and nurses.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until Tuesday, March 19, when we will meet here in Dirksen 116 at 9:30 to hear testimony from the National Institutes of Health. On the 19th we will have the Director's overview as well as the Directors of the National Cancer Institute, the National Heart, Lung, and Blood Institute, and the National Institute of Dental Research.

[Whereupon, at 11 a.m., Wednesday, March 6, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, March 19.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

TUESDAY, MARCH 19, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:43 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Proxmire, and Byrd.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR

ACCOMPANIED BY:

DR. WILLIAM F. RAUB, DEPUTY DIRECTOR FOR EXTRAMURAL RESEARCH AND TRAINING, NATIONAL INSTITUTES OF HEALTH
NORMAN D. MANSFIELD, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT, NATIONAL INSTITUTES OF HEALTH
WILLIAM R. BELDON, ACTING DIRECTOR, DIVISION OF HEALTH BUDGET ANALYSIS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING STATEMENT

Senator WEICKER. The committee will come to order. I want to apologize for my tardiness.

In any event, today the subcommittee begins 3 days of hearings focused on the President's proposed budget for the National Institutes of Health, the world's foremost biomedical research institution.

NIH's successes over the past 50 years have literally changed the face of this Nation and, one might also say, of the entire world. Over the years, it has supported the work of 85 Nobel laureates—provided cures, preventive treatments, and understanding of diseases that debilitated mankind for centuries. The money this Government invested in NIH-sponsored research has been returned to the economy 13 to 16 times by lowering treatment costs for disease and increasing the productivity of our citizens who have or may have contracted these diseases.

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We are now being told of incredible advances in genetics, immunology, neurology, and cancer, just to name a few areas of concern.

Yet, despite this long history of success, Congress has to reeducate the administration every year. This year not only are you attempting to stamp out agreed-upon growth in the fiscal year 1985 budget, you are proposing a 1986 budget that is $282 million less than last year.

To make matters worse, you are claiming a 2-percent increase for fiscal year 1986 based on funds borrowed from the past.

The level of this year's growth was arrived at independently in both Houses of Congress based on extensive evaluation of need and potential. When I questioned Secretary Heckler about this, she responded by citing the budget crisis preached by OMB.

I don't buy it. The President's budget for research and development approaches $60 billion. Almost 70 percent is earmarked for defense, while 8 percent goes to NIH. Defense R&D has grown 102 percent since 1981 while civilian R&D has grown by 2 percent.

Now, Dr. Wyngaarden, you yourself have said that the momentum of discovery must be maintained and the successes of today result from the investments of the past. Yet, in every one of the past 3 years you have defended a budget request for NIH that restricts growth, impedes development, and demoralizes a community of scientists that is responsible for the success of the future.

I want to say, having made those remarks, insofar as the administration is concerned, I realize when these matters are presented to us, they are presented particularly eloquently by you, Dr. Wyngaarden. I also have to say that I and my staff have received nothing but the utmost cooperation from you and those who work alongside you. I don't want to jinx you in the eyes of the administration, but I think you are a damn good director of NIH.

Beginning today, however, substance will replace arithmetical measures in determining the fiscal year 1986 direction of NIH. We've heard from the budgeteers—now it's time to hear from the men of science in whom direction of NIH has been entrusted.

ADJUSTMENTS IN 1985 APPROPRIATION

However, I have some good news this morning and also a question to pose to you, Dr. Wyngaarden, before we get started in your testimony: I have in hand—a copy will be made available to you before you leave today—a letter dated March 18, 1985, from the Comptroller General of the United States. I am going to ask you a question, indeed a concern of the subcommittee and a majority of the Senate. As you are aware, during the conference on the fiscal year 1985 appropriations bill, Senate and House conferees agreed on a $5.15 billion NIH budget, with the intention that NIH fund 6,526 research grants during that fiscal year.

The President signed that bill into law. Then, in the face of the conference agreement your Department announced its intention to fund, in fiscal year 1985, only 5,000 NIH grants, of which 646 were to be funded on a 3-year basis. The General Accounting Office, which has

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the authority to surcharge disbursing officers for illegal expenditures, has now declared in a written opinion, and I quote:

> * * * the executive branch plan to fund some 646 NIH research grants on a 3-year basis with fiscal year 1985 funds is unlawful because of the absence of specific statutory authority such as actions that violate 31 United States Code section 1502.

We have also been advised that an officer or employee of an executive agency who obligates appropriations for a period beyond the period for which they are available is in violation of the Anti-Deficiency Act. A violation of this act is a criminal offense punishable by fine, imprisonment, and removal from office.

Under those circumstances, I would ask your assurance either here today or certainly when you review the letter, no NIH research grants made in 1985 will be multiyear funded. I want to tell you, this issue has been one I received probably the most interest in since I have chaired the committee. We have been waiting for an opinion on the matter. We will now be able to see the congressional intent fulfilled. It is also my intention, any disbursing officer who does disburse funds under those circumstances does so not as institutional business, but personal business.

So, with those opening remarks, I am looking forward to your opening statement. [Laughter.]

And questions will follow, again, I repeat, I think this letter from GAO really reflects on OMB more so than it does on you.

Proceed.

BUDGET REQUEST

Dr. WYNGAARDEN. Thank you, Mr. Chairman.

Before I start, I would like to introduce members of the panel. On my far right is Mr. William Beldon who is Acting Director of the Division of Health Budget Analysis in the Department. Next is Mr. Norman Mansfield, Director of the Division of Financial Management at NIH, and on my left, Dr. William Raub, Deputy Director for Extramural Research and Training at NIH.

Mr. Chairman, it is my privilege once again to present testimony on behalf of the President's budget request for the NIH. These hearings provide my associates and me an opportunity to express our thanks to you for your consistent support of the program of NIH as well. In addition, Mr. Chairman, speaking for my colleagues at the NIH, I wish to add our word of tribute to the memory accorded to the late Senator Lister Hill, who championed the cause of biomedical research with great foresight and effectiveness during his distinguished career as chairman of this subcommittee.

As you already pointed out, Mr. Chairman, for more than 40 years, NIH has been the principal source of support for health-related research conducted in America's universities and medical schools, currently supplying almost two-thirds of the funding for such research. The research supported by the NIH, together with that conducted in its own laboratories, has had a profound and beneficial influence on the mod-

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ern practice of medicine and on the state of health of people throughout the Nation.

When I appeared before this subcommittee last year, I expressed our appreciation for your key role in making it possible for NIH to acquire the 11-acre convent property on the western edge of the NIH campus, now designated as the Mary Woodard Lasker Center for Health Research and Education. I am happy to report to you now that, because this property was available, the NIH has been able to launch an important new program whose funding comes not from the Government but from the private sector. Under an agreement with the Howard Hughes Medical Institute, we are establishing a cooperative program that will afford about 30 students each year an opportunity to engage in research in the course of their medical school training. We are convinced that this kind of early exposure to research is an important factor in attracting bright and dedicated medical students into biomedical research.

The directors of the constituent bureaus, institutes, and divisions of NIH will present further information about accomplishments in their respective areas of responsibility. They also will outline their program plans for the coming year in the light of the President's budget. I will confine my comments on the budget to matters that affect the NIH as a whole, addressing particularly the novel features of this year's proposal.

In connection with the GAO opinion that you have just read us, I would like to mention that, after a review in OMB, the Department developed a different point of view. Clearly, we will be very much interested in reading the GAO opinion and studying it, but until instructed otherwise, I need to proceed on the basis of the President's budget, which was announced in February.

Senator WEICKER. I would just point out to you again here, as you read the letter, the difficulties, some of the points that we raised came down in your favor in the sense of, for example, had the funds not been spent at all, that you would be in violation of the law. The fact you are spending funds for purposes that don't fall in a bonafide need rule apparently puts it in violation of 31 United States Code, and I repeat—I repeat—because I have too many good friends, youself included, over at NIH, anybody that does go ahead and disburse these funds does so at their personal risk, and I can assure you it is a matter that I will intend and the committee will intend to pursue. That means your house, your car, not the Government's, not your office. [Laughter.]

Not the Government vehicle; your house, your car, your bank account is going to be involved in this.

The letter of response here is very complete on all points, all of them really coming down in your favor with the exception of the point that I have raised. It would seem to me it would not be very prudent to proceed with any such action until this is discussed as between yourselves and the General Accounting Office and certainly this committee.

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DELAY IN MULTIYEAR FUNDING

Dr. WYNGAARDEN. As you may know, Mr. Chairman, Secretary Heckler testified that we would delay any forward funding until July 1. Before the House subcommittee I was asked whether we could delay until September 1; while that would present certain additional problems, we could mechanically do that. Of course, until this issue is resolved, we are withholding certain funds and will do so until the issue is resolved.

Senator WEICKER. Again, I think what you have got to do is live with the law that was signed. As I look upon probably the resolution of the problem, it is that you are going to have to live with what was done in fiscal year 1985 law, and then, indeed, pull back for whatever need in fiscal year 1986, and that issue can be resolved legislatively and/or with the executive branch of Government. What is at issue is what you are doing with the fiscal year 1985 funds. The fiscal year 1986 is a matter of debate and that can be ironed out.

I put you and, as I said, the Department on notice now as to the letter. I repeat, aside from whatever differences we have as a matter of policy, I don't want your you-know-what in the crack on this thing. I forewarn you.

Dr. WYNGAARDEN. I understood you clearly, Mr. Chairman. [Laughter.]

FORWARD FUNDING PROPOSAL

With that, if we may proceed on the premise of my present instructions, as you know the basis for the development of the 1986 budget for the NIH is the administration's policy essentially to freeze domestic programs at the 1985 funding level. To accomplish this purpose without upsetting the stability of our major research support program requires adjustments in 1985 spending with regard primarily to the funding of research project grants and research centers.

The 1985 revised budget will fund 5,000 new and competing renewal research project grants and approximately 12,172 continuation awards arising from competition in previous years. As you have already noted, about 646 of these 5,000 new and competing renewal awards will receive funding in 1985 for 3 years of support. This multiyear funding policy is intended to avoid significant fluctuations in the number of research grants that NIH is able to support and to lower future noncompeting requirements.

The 1985 budget also includes $482,144,000 for 500 research centers. This represents an increase of four centers over 1984 and includes support for three new research centers on Alzheimer's disease and related disorders. Approximately 45 of the 500 centers will be awarded 2 years of support from 1985 funds.

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NIH BUDGET FOR 1986

Turning now to the 1986 budget, the request for NIH is $4,852,680,000, representing a decrease of $282,048,000 from the comparable 1985 level. The budget request will support 12,957 full-time equivalent staff positions, which is a reduction of 150 from the 1985 level of 13,107, and a reduction of 704 from the 1984 actual usage of 13,661. The budget also assumes savings of $29.8 million in administrative costs and $19.1 million as the result of the proposed 5-percent reduction in pay costs.

The request supports an estimated 5,000 new and competing renewal research project grants and 11,242 noncompeting research project grants. Direct costs of research project grants in 1986 will be funded on the average at the historical levels of 97 percent of costs recommended by study sections for new and competing renewal awards, and 99 percent of committed amounts for noncompeting awards.

The 1986 request includes $412,391,000 to fund 455 research centers. The 45 centers that were multiyear funded in 1985 will remain active in 1986, so the total would remain at 500.

As part of the administration's effort to hold domestic programs at the 1985 level, indirect cost rates associated with research grants will be held at the 1985 rate. It is estimated that this measure will save about $23 million.

We also intend to support approximately 9,900 research trainees in 1986, which is the same number as in 1985.

Budget authority of $561,653,000 is requested for the Intramural Research Program; the decrease of $17,638,000 from the 1985 level represents savings resulting from Governmentwide reductions in administrative costs and the proposed 5-percent pay cut.

I will be pleased to answer any questions that you may have, Mr. Chairman.

PREPARED STATEMENT

Senator WEICKER. Thank you very much.

We will inset your prepared statement in the record and then we will proceed to some questions.

[The statement follows:]

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STATEMENT OF DR. JAMES B. WYNGAARDEN

Once again it is my privilege to present testimony on the President's budget request for the National Institutes of Health. In discussing the proposal for Fiscal Year 1986, I will also touch briefly on the recent progress of biomedical research. It is especially gratifying to report such advances in this setting, Mr. Chairman, because you and the members as well as the staff of the Subcommittee have shown such personal interest in the role of biomedical research in improving the health of the American people. These hearings also provide my associates and me an opportunity to express our thanks to you for your consistent support of the programs of the NIH.

For about 40 years, the NIH has been the principal source of support for the health-related research conducted in America's universities and medical schools, currently supplying almost two-thirds of the funding for such research. The research supported by the NIH, together with that conducted in its own laboratories, has had a profound and beneficial influence on the modern practice of medicine and on the state of health of people throughout the Nation. The vision and persistence of the many who have championed the NIH over the years have been more than amply vindicated.

While the improvement of health is and will continue to be our central purpose, there has been substantial interest of late in a related development, one not foreseen when NIH was established. That is, the beginning of an entirely new industry based on the results of fundamental research for which the Agency was largely responsible. The influence of NIH on biotechnology has been substantial and extensive. A local example of this influence was reported in a recent article in the Washington Post that credited NIH research with helping to spawn more than 200 biotechnology companies in the Washington area alone. But the influence is international in scope. Recent government and private industry studies attest to the NIH role in fostering this Nation's leadership in biotechnology. The NIH Director's Advisory Committee will devote the entire agenda of its June 1985 meeting to a discussion of that role.

When I appeared before this Committee last year, I expressed our appreciation for your key role in making it possible for NIH to acquire the 11-acre convent property on the western edge of the NIH campus, now designated as the Mary Woodard Lasker Center for Health Research and Education. I am happy to report to you now that because this property was available, the NIH has been able to launch an important new program whose funding comes not from the government but from the private sector. Under an agreement with the Howard Hughes Medical Institute, we are establishing a cooperative program that will afford about 30 students each year an opportunity to engage in research in the course of their medical school training. The students will be chosen in nationwide competition and will spend six months to a year in research training on the NIH campus under the guidance of leading NIH scientists. The Hughes Institute will support this program at a cost of about $10.5 million for the first five years. Recruitment began last fall with the first group of students to enter the program in the fall of 1985. A gratifying number of first-rate students applied.

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We are convinced that this kind of early exposure to research is an important factor in attracting bright and dedicated medical students into biomedical research. Much of today's most challenging research requires individuals who are both medically knowledgeable and scientifically trained.

In commenting on the essential relationship existing between the conduct of research by the NIH and the practice of medicine, I should take note of two events of the past year that are symbolic of an increasing awareness of such ties.

A special issue of the Journal of the American Medical Association, last October, devoted almost 50 pages to descriptions of the entire range of activities of the NIH to tell, in the words of the news editor, "what the existence of the NIH means for the practice of medicine."

In January 1985, another widely circulated publication, Medical World News, devoted much of its 25th anniversary issue to the National Institutes of Health. In the lead editorial, the comment was made that "few of the mainstays of clinical practice today have not had their origins in NIH research . . ."

Communication with both the health care and the biomedical research communities, making full use of advanced technology, continues to be an important function of the NIH's National Library of Medicine.

Briefly, I will mention a few of the highlights of research accomplishments by scientists working in or supported by the various components of the NIH:

- There has been important progress on acquired immune deficiency syndrome (AIDS), particularly from the NIH laboratory of Dr. Robert Gallo. Dr. Gallo and French scientists independently discovered a virus that is the causative agent of the disease. More recently, the entire genetic structure of the virus has been mapped. This opens the way for new treatment opportunities and prevention strategies and will accelerate work aimed at vaccine development. Moreover, Dr. Gallo's method for detecting the AIDS virus antibody has led to the development of commercial test kits to screen blood and thus protect the Nation's blood supply.

- NIH intramural scientists, also using genetic engineering techniques, have cloned the entire gene for the major antigen on one life cycle stage of the human malaria parasite Plasmodium falciparum. This discovery will allow preparation of sufficiently large quantities of the antigen to test for its potential use in a vaccine. Malaria is an important and growing world problem, due to increasing numbers of drug-resistant parasites and insecticide-resistant mosquitoes that are overwhelming ongoing control efforts.

- A study supported by NIH at several centers has shown that clots in blood vessels of the heart can be dissolved by administration of an agent rt-PA (tissue-type plasminogen activator) in patients developing heart attacks. This trial

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confirms that the agent can reopen blocked vessels quickly and probably without some of the side effects of other clot-dissolving agents. The treatment, with further study, may represent a major advance in the care of the 680,000 patients annually who experience a blood clot in the coronary vessels.

- NIH intramural scientists have succeeded in developing a vaccine that promises to be effective against herpes simplex virus--the virus that causes "cold sores" or "fever blisters" on the skin or mucous membranes. The researchers used a technique developed at NIH--whereby herpes virus DNA is inserted into Vaccinia virus to produce a recombinant or hybrid virus. The genetic material of hepatitis B, of rabies, and of almost any organism can be inserted into Vaccinia virus. For rabies, influenza, and hepatitis B, very good protection can be induced in experimental animals.

- In another clinical advance, NIH intramural scientists have found that the drug cyclosporine can rapidly reduce eye inflammation in patients with posterior uveitis, a serious disease that can severely limit vision. In most cases, vision also improved with control of inflammation.

- Scientists at NIH and other supported by NIH grants continue to discover more potential cancer-causing genes (oncogenes) and "map" their locations on human chromosomes. Such studies continue to confirm the role of these oncogenes in the origins of cancer. Further study may reveal ways to destroy or block the products of these oncogenes, and result in advances in cancer prevention, diagnosis and treatment.

The directors of the constituent bureaus, institutes, and divisions of NIH will present further information about accomplishments in their respective areas of responsibility. They also will outline their program plans for the coming year in the light of the President's budget. I will confine my comments on the budget to matters that affect the NIH as a whole, addressing particularly the novel features of this year's proposal.

The basis for development of the Fiscal Year 1986 budget for the NIH is the Administration's policy essentially to freeze domestic programs at the 1985 funding level. To accomplish this purpose without upsetting the stability of our major research support program requires adjustments in FY 1985 spending with regard primarily to the funding of research grants.

Research project grants to individual investigators continue to receive the highest priority because they support the primary source from which fundamental discoveries emerge. Thus they represent the key mechanism in Federal support of biomedical research. The 1985 budget will fund 5,000 new and competing renewal research project grants and approximately 12,172 continuation awards arising from competition in previous years. About 646 of the 5,000 new and competing renewal awards will receive funding in 1985 for three years of support. This multiyear funding policy is intended to avoid significant fluctuations in the number of grants NIH is able to support and to lower future noncompeting requirements.

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The 1985 budget also includes $482,144,000 for 500 research centers. This represents an increase of four centers over 1984 and includes support for three new research centers on Alzheimer's disease and related disorders. As with research project grants, some of the research centers will receive multiyear support. Approximately 45 of the 500 centers will be awarded two years of support from FY 1985 funds.

Turning now to the 1986 budget, the request for NIH is $4,852,680,000, a decrease of $282,048,000 from the comparable 1985 level. Examined from a program level perspective, however, the request represents close to a 2 percent increase over 1985. This increase reflects the 1986 budget authority, plus the second year resources provided from 1985 funds. The budget request will support 12,957 full-time equivalent staff positions, a reduction of 150 from the 1985 level of 13,107, and a reduction of 704 from the 1984 actual usage of 13,661. The budget also assumes savings of $29.8 million in administrative costs and $19.1 million as the result of the proposed 5 percent reduction in pay costs.

The request supports an estimated 5,000 new and competing renewal research project grants and 11,242 noncompeting (i.e., previously competed) research project grants. Including the estimated 646 grants which were multiyear funded in 1985, the total number of active research project grants in 1986 will be 16,888. Direct costs of research project grants in 1986 will be funded on the average at the historical levels of 97 percent of costs recommended by study sections for new and competing renewal awards, and 99 percent of committed amounts for noncompeting awards. The NIH aggregate average costs will be approximately 6.0 percent higher than 1985 for new and competing renewal awards, and about 7.8 percent higher for noncompeting continuations.

The 1986 request includes $412,391,000 to fund 455 research centers. The 45 centers that were multiyear funded in 1985 will remain active in 1986, thus a total of 500 centers will be ongoing in 1986, the same number as will be supported in 1985. The budget assumes the same average costs in 1986 as in 1985.

As part of the Administration's effort to hold domestic programs at the 1985 level, indirect costs rates associated with research grants will be held at the 1985 rate. It is estimated that this measure will save about $23 million.

NIH will support approximately 9,500 research trainees in 1986; the same number is estimated to be supported in 1985. This represents about 94 percent of the level recommended by the National Academy of Sciences for the NIH. Consistent with the overall freeze guidance, stipend levels are maintained at their 1985 level which represents an increase over 1984.

Budget authority of $561,653,000 is requested for intramural research in 1986. The decrease of $17,638,000 from the 1985 level represents the savings resulting from government-wide reduction in administrative costs and the proposed 5 percent paycut.

In summary, the 1986 request for the NIH represents a realistic level of Federal support for biomedical research and

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research training in the context of the rising Federal deficit and the need for Federal fiscal austerity. The 1986 request reflects the Administration's commitment even in times of scarce resources to a stable program of biomedical research and research training.

I will be pleased to answer any questions you may have.

Biography of Dr. James B. Wyngaarden

October 19, 1924. East Grand Rapids, Michigan

Education: Calvin College, 1942-43; Western Michigan University, 1943-44. M.D., University of Michigan Medical School, 1948.

Professional History: 1948-52, Intern and Resident, Massachusetts General Hospital, Boston. 1952-53, Visiting Investigator, Public Health Research Institute of the City of New York, New York. 1953-54, Investigator, National Heart Institute, NIH; 1954-56, National Institute of Arthritis and Metabolic Diseases, NIH. 1954-56, Clinical Instructor in Medicine, George Washington University, Washington, D.C. 1956-59, Associate Professor of Medicine, Duke University Medical Center, Durham, North Carolina. 1959-61, Associate Professor of Medicine and Biochemistry, Duke University. 1961-65, Professor of Medicine and Associate Professor of Biochemistry, Duke University. 1963-64, Visiting Scientist, Institut de Biologie-Physiochemique, Paris. 1965-67, Frank Wistar Thomas Professor and Chairman, Department of Medicine, and Professor of Biochemistry, University of Pennsylvania School of Medicine, Philadelphia. 1965-67, Physician-in-Chief, Medical Service, Hospital of the University of Pennsylvania. 1967-82, Frederic M. Hanes Professor and Chairman, Department of Medicine, Duke University. 1967-82, Physician-in-Chief, Medical Service, Duke University Hospital. 1981-82, Chief of Staff, Duke University Hospital.

Professional Organizations: American Academy of Arts and Sciences, American Association for the Advancement of Science, American Board of Internal Medicine, American Clinical and Climatological Association, American College of Physicians, American Federation for Clinical Research, American Rheumatism Association, American Society for Clinical Investigation, American Society of Biological Chemists, Association of American Physicians, Endocrine Society, Institute of Medicine, Interurban Club, National Academy of Sciences, Southern Society for Clinical Investigation, Sigma Xi, Council of the Government-University-Industry Research Roundtable.

Honors, Awards: University Scholar in Professional Schools (Medical), University of Michigan, 1946. Alpha Omega Alpha (University of Michigan), 1947. Cum laude with First Honors, University of Michigan, 1948. Dalton Scholar in Medicine, Massachusetts General Hospital, 1948. Consultant to the Durham Veterans Administration Hospital, 1956-65 and 1967-82. Honorary Membership in the Italian Society of Rheumatology, 1961. Consultant to the Philadelphia Veterans Administration Hospital, 1965-67. Consultant to the Office of Science and Technology, Executive Office of the President, 1966-72. Sesquicentennial Award, University of Michigan, 1967. Appointed to the President's Science Advisory Committee, 1972. Consultant to the Food and Drug Administration, 1972-73. Modern Medicine Award for Distinguished Achievement, 1974. Election to the National Academy of Sciences, 1974. North Carolina Governor's Award in Science, 1974. Appointed to the President's Committee for the National Medal of Science, 1977-80. Founder's Medal, Southern Society for Clinical Investigation, 1978. The John Phillips Memorial Award, American College of Physicians, 1980. Honorary Membership in the Sociedad Medica de Santiago de Chile, 1981. Fellow of the Royal College of Physicians of London, 1984. Distinguished Alumnus Award, Western Michigan University, 1984.

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AWARD RATES

Senator WEICKER. The number of peer reviewed grant applications has increased from 7,702 in 1975, to about 16,000 in 1985. The percentage of funded applications has fluctuated from a high of 61 percent in 1975 to a low of 30 percent in 1985.

Budget considerations aside, what percentage of approved applications should be funded in order to achieve full benefit from your intra- and extramural research communities?

Dr. WYNGAARDEN. I have in the past stated that, if there were ample funds, an award rate in the range of 45 percent would be desirable.

Senator WEICKER. Can you give me either now or for the record the funding that would be required to meet that optimism, insofar as your opinion is concerned, budget considerations aside? I might add in my question, there is no point repeating that aspect of it.

Dr. WYNGAARDEN. We will be happy to provide that for the record.

[The information follows:]

COST ASSOCIATED WITH 45-PERCENT AWARD RATE

A 45-percent award rate in 1986 would mean that approximately 7,800 new and competing research project grants would be funded. The estimated cost of 7,800 grants is $1,183 million.

BENEFITS OF BIOTECHNOLOGY

Senator WEICKER. There is a great deal of excitement being generated by the biological revolution and how all of these new discoveries are going to be useful to medical practice and to society as a whole.

I have also been reading that useful commercial application opportunities are spawning a new biotechnology industry that would bring favorable economic benefits to the citizens of this country.

Can you review some of the history and project for us some of the benefits that will occur?

Dr. WYNGAARDEN. The bulk of the work that has given rise to the explosion in biotechnology has been supported by the NIH over the past 20 years. In 1985 we estimate approximately $570 million in funding of extramural and intramural projects that are directly related to biotechnology and probably another $1.3 billion in support of science indirectly related to biotechnology. These figures represent well over one-quarter of our total portfolio of research support. Thus the NIH is a major player in this development.

At present, there are substantial benefits from that research. Biotechnology is opening up new avenues of understanding. For example, much of the work on oncogenes results from developments in biotechnology. There are also new products being introduced, including insulin and other hormones. Just recently the gene for factor VIII has been cloned, opening up new methods of production of the clotting factor for hemophiliac patients, which will not only increase the availability of that substance but should provide a substance free from risk of contamination.

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The impact on biology and medicine is undoubtedly already profound and will be more so.

But beyond that, these developments are beginning to affect in a substantial way the agricultural industry. We look for major innovations in plant resistance to molds, pests, and frost through genetic engineering.

The developments in the petrochemical industry may be very substantial. Potential cleanup of oil spills by engineered organisms has been cited as one possible development. I think we are just on the threshold, Mr. Chairman, of very substantial developments in many industries that can be attributed to this basic support that originally derived chiefly from the NIH.

Senator WEICKER. I agree with you. I think certainly the statistics support both your recitation and facts and also your optimism for the future. I suppose what bothers me is the funding requests are not equivalent to either the record of success or potential for success.

Dr. WYNGAARDEN. This remains a very high priority area. I would anticipate the figures I have given of current expenditure will essentially be correct for 1986 as well.

Senator WEICKER. What is the total NIH budget request?

Dr. WYNGAARDEN. The NIH budget request for 1986 is $4,852,680,000.

Senator WEICKER. Roughly $5 billion, and yet all of which deals with the matter of life. This afternoon in one vote, one weapons system of destruction, we ask for $3 billion just like that. That is why I think these matters really should be argued and debated, not in the sense it is all one way to the exclusion of the other, but it would seem to me anyway that both the strength and the future strength of the Nation really relate to what we can do in terms of life. That is what the next 3 or 4 days are going to be all about.

Also, I am not willing to march to marching orders from the administration, either this morning, or this afternoon. [Laughter.]

STAFFING LEVELS

The fiscal year 1985 conference report directs the NIH to maintain staffing levels at not less than 13,507 Federal full-time equivalent positions. What is your present number of FTE's?

Dr. WYNGAARDEN. Approximately 13,200.

Senator WEICKER. Do you plan to comply with the stated intent of Congress and maintain 13,507 FTE's?

Dr. WYNGAARDEN. Our instructions call for a reduction to 13,107 in 1985. The 1986 request will support 12,957, which is a decrease of 550 from the 1985 appropriations figure, and 704 from the actual usage of 13,661 in 1984.

Senator WEICKER. Is that your decision or OMB's?

Dr. WYNGAARDEN. It was relayed to us through the Department.

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ANIMALS IN RESEARCH

Senator WEICKER. We have been receiving a great deal of mail concerning the use of animals in research. Are you satisfied that the Government-sponsored research is monitored sufficiently to ensure animals are used properly?

Dr. WYNGAARDEN. Yes; I am in general. There are some points of the total program that can be improved. For example, we have been conducting some random site visits to give us better insight into the degree of compliance with the assurances we have received from the institutions that are funded; on the basis of that, we have been able to suggest some future improvements in the standards that NIH has promulgated for such assurances.

At present about 23 percent of the institutions we fund are actually accredited by AAALAC. Another 48 percent are self-accreditied and are in compliance with the NIH guide. About 18 percent have given NIH the assurance of a plan to upgrade where they have some deficiencies in the facilities. There is progress to be made.

INCREASED COST OF GRANTS

Senator WEICKER. The rate of inflation has been hovering at about 4 percent in the past 1½ years. Yet your budget justifications indicate you are estimating the cost increase of continuing grants at 7.8 percent. How come you are almost double the rate of inflation?

Dr. WYNGAARDEN. That estimate comes from a projection based on past experiences. The rate of increase of costs of research traditionally has run a little ahead of the inflationary figure. Our estimates are derived from projections of actual receipts and experience in that matter.

INTRAMURAL RESEARCH PROGRAM

Senator WEICKER. In fiscal year 1985, you received a $40 million increase for the intramural program. Can you describe to the committee the program growth achieved with that $40 million?

Dr. WYNGAARDEN. I would like your permission to do that for the record, if I may, Mr. Chairman.

Senator WEICKER. All right.

[The information follows:]

INCREASE IN INTRAMURAL RESEARCH PROGRAM

The 1985 appropriation provided a $40.6 million increase over the 1984 level for intramural research. Of this amount, $1.6 million has been placed in reserve in accordance with section 515 of the Treasury Postal Service Appropriation Act and $3.8 million is proposed for rescission as part of the Deficit Reduction Act, leaving a net increase of $35.2 million over 1984.

Most of this increase, approximately $30 million, will cover the costs of inflation in equipment and supplies, and the 1985 costs of the 1984 pay raise and other personnel costs such as within-grade increases. Coverage of these costs will enable the 1984 operating level to be maintained in 1985. The remaining $5 million will be applied to several modest program enhancements in high priority areas.

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INDIRECT COSTS

Senator WEICKER. In fiscal year 1986, you are proposing a freeze of indirect costs at the fiscal year 1985 level. How will the freeze impact upon the universities who have participated in the national effort in biomedical research?

Dr. WYNGAARDEN. Growth of indirect costs has been fairly steady as a fraction of total grant dollars, averaging about 0.5 or 0.6 percent increase per year since the early 1970's. The current estimated indirect cost rate is about 31.7 percent, which is about one-half percent higher than 1984. The 1986 budget proposal would freeze the rate at 31.7 percent overall. It would freeze the rate at whatever it was for the individual recipient institution for 1985.

Senator WEICKER. Why do the indirect costs appear to vary from university to university? Do you have a study under way on this matter?

Dr. WYNGAARDEN. No; we are not currently conducting a detailed study. The entire matter of indirect costs, as you know, has been an active one and a contentious one for some years. Proposals for containing indirect costs have resulted from a study in the previous year; the recommendations of that proposal plus our comments have been forwarded to the Department and to OSTP, where it is my understanding the action presently lies. We have not heard from them as to any further proposals that will be made.

At the present time, we are paying the indirect costs that have resulted from the traditional appraisals and audits.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions. We have a meeting with your boss, and by that I don't mean David Stockman, I mean the President. I have further questions for response to the record. You will be with us during the balance of this week.

What I would like to do is have these further questions presented to you for response to the record and move on to the other directors of your various institutes. You might contemplate trying to respond a little more specifically to this letter when we see each other on Thursday.

Dr. WYNGAARDEN. Fine. I can study it from now until then.

Senator WEICKER. Thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

ADJUSTMENTS TO 1985 APPROPRIATION

Question: Before we get into the Administration's 1986 budget request for NIH, I want to spend a moment on the 1985 appropriation.

Congress passed and the President signed a 1985 appropriations bill that provided over $5.1 billion to the National Institutes of Health. We provided funds for over 6,500 new and continuing research grants and 533 research centers.

Now let's take a look at what the Administration is proposing to do to this year's budget.

- By limiting the number of grants to 5,000 and the number of centers to 500, they are borrowing over $238 million from 1985 to pay the bills in 1986.

- They are setting aside or proposing for rescission $15.2 million.

- They are requiring the NIH to absorb a pay raise of $13.4 million.

A total in excess of $266 million is being stripped from the 1985 budget.

Dr. Wyngaarden, when were you first notified of the OMB directive limiting the number of grants and centers?

Answer: I was notified of the OMB directive to limit the number of grants and centers when I received the OMB allowance for 1986. This occurred in late December 1984.

Question: Were you consulted before the OMB issued its directive?

Answer: No, I was not consulted.

Question: Did you respond to the directive?

Answer: When I was notified of the directive, I was also instructed that there would be no opportunity for appeals and that the NIH was expected to implement the multiyear funding policy as soon as practicable.

Question: Did you appeal the rescission and pay absorption decisions?

Answer: Yes; the NIH appealed the rescission to OMB through the Office of the Secretary, which resulted in a reduction of the amounts originally proposed. The decision to absorb the pay raise was discussed with the Office of the Secretary, but my understanding is that no appeal was made to OMB.

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GRANT CYCLE

Question: I understand that grant awards are made several times during the year, it that correct?

Answer: The NIH typically has three review sessions during the year to render formal approval of grants for funding. These sessions are in September/October, January/February, and May/June. In some cases a special session may be held in August or September. The awarding process, however, takes place throughout the year.

Question: At what point in the cycle did the directive by OMB take effect?

Answer: The NIH was informed of OMB's directive in December 1984 as part of the Administration's allowance for the 1986 budget. The multiyear funding policy was intended to take place as soon as practicable in fiscal year 1985.

Question: What percentage level of approved grants were funded before the directive?

Answer: Before the directive, the NIH appropriation for 1985 provided for 6,526 new and competing research project grants, which would result in an award rate of about 37.5 percent.

Question: What was the percentage level after the directive?

Answer: The Administration's directive for 1985 provided for 5,000 new and competing research project grants, which would result in an award rate of 28.8 percent.

EFFECT ON INDIVIDUAL RESEARCHER

Question: What have been the effects of the 5,000 grant level on the individual researcher?

Answer: The effect of interrupted support could be serious from the standpoint of the scientist himself, his technical staff, fellows, graduate students, and the research. On occasion, research teams may have to be disbanded. In most cases, his technicians are supported entirely through his grant funding and consequently must find other employment. In addition, graduate students and fellows studying with an investigator are usually supported through his grants. Their training can be interrupted by loss of grant support, particularly if the investigator must leave his position. Interim sources of support may be available while the investigator revises his application in hopes of a better score in a subsequent round.

Question: How many continuing research projects are affected? How many have lost technicians and momentum? How much on-going, successful, productive research has been hurt by this Directive?

Answer: Since the altered award pattern has not yet been implemented, it is not possible to say precisely how many continuing research projects will be affected, including the impact on research teams and on scientific momentum.

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BIOTECHNOLOGY

Question: There is a great deal of excitement being generated by the "biological revolution" and how all of these new discoveries are going to be useful to medical practice and to society as a whole.

I have also been reading that useful commercial application opportunities are spawning a new biotechnology industry that would bring favorable economic benefits to the citizens of this country.

Why do you think the President's projections of balancing the budget through economic growth appear to ignore the investment opportunities presented by biomedical research?

Answer: It is widely acknowledged that the NIH has provided the bulk of support in the United States for basic biomedical research that has proved crucial to the development of biotechnology. The NIH has also contributed substantially to the development of the manpower needed both by universities and industry to sustain research progress. In addition, the NIH--through the Recombinant DNA Advisory Committee (RAC)--has provided a mechanism for the oversight of the safety of biotechnology research.

NIH support for research in biotechnology may be classified into two categories:

- o Research directly related to biotechnology, which involves genetic manipulation, cloning of DNA, use of special techniques to isolate and detect DNA, creation of hybridomas and production of monoclonal antibodies, and computer methods used to analyze DNA and protein sequences; and

- o Research underlying biotechnology, which refers to that broader science base of research underlying the new biotechnology and includes free-ranging investigations in genetics and molecular biology, cell biology, and immunology.

The amounts allocated in these areas are as follows:

	(dollars in thousands)		
	1984 Actual	1985 Estimate	1986 Estimate
Directly related.....	$ 521,786	$ 570,467	$ 548,011
Broader science base..	1,120,439	1,258,139	1,197,571
Total.....	1,642,225	1,828,606	1,745,582

Question: What role do you feel the NIH should play in the development of biotechnology programs?

Answer: Clearly, the NIH will continue its role as the principal source of research and training in, and related to, biotechnology.

The NIH is currently examining its functions and activities in this area with the goal of identifying ways in which we can further advance the burgeoning biotechnology industry. Recently we met with representatives of the Industrial Research Institute (IRI), an asso-

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ciation of some 276 industrial research and development companies, to discuss their interest in maximizing the return on the nation's R&D investments. This meeting served as the initial exchange of views leading to potential further cooperation between the NIH and industrial R&D programs.

The NIH is also participating with the National Science Foundation in the funding of a new center grant award in biotechnology at the Massachusetts Institute of Technology. The National Institute of General Medical Sciences and the National Cancer Institute will be providing approximately $100,000 and $50,000, respectively, per year primarily for the support of training of individuals who will combine engineering and biology in addressing problems in the area of bioprocessing.

To aid us in consideration of the overall role of the NIH in biotechnology, the June meeting of the Advisory Committee to the Director (DAC) will be extended to 2 days and devoted exclusively to the question of the NIH role in fostering the nation's leadership in biotechnology. Discussion will be focused on: historical development and future prospects of biotechnology; the Federal science policy for biotechnology; NIH and the support of training in biotechnology; risk assessment and risk management; barriers to industrial competitiveness (manpower, financial, regulatory, and information access); and the NIH's role in fostering biotechnology. Speakers representing all segments of the biotechnology spectrum from government, universities, and industry have been invited to describe their experiences and to lead discussion. This meeting is expected to provide the factual background and conceptual framework to begin formulating agency strategies and program emphases that will assure the continuing health of the science base necessary to support biotechnology.

KNOWLEDGE GROWTH VS. BUDGETARY RESTRICTION

Question: Biomedical research has given this nation tremendous benefits over the past 50 years. We are told of exciting advances yet to come and the need for increased Federal support. What are the areas of research that will create the most excitement over the next year or so?

Answer: Recombinant DNA technology, an exciting tool with which we can transfer hereditary units from one species to another, continues to find its way into a myriad of applications. Such developments have provided a powerful new research technique and have spawned a dynamic new industry with immense potential. It permits, for example, bacteria to become "factories" that produce substances of biological, agricultural, and medical importance. This technique has already led to the synthetic production of human insulin, somatostatin, and growth hormone. Recombinant DNA technology can also be used to produce large quantities of pure antigen which, in turn, can be used as vaccines for immunization against infectious agents.

Also, scientists are now cloning the genes for enzymes, proteins, and peptides of importance. The normal gene can then be studied to determine its structure and regulation. Using the normal gene as a probe, scientists can now examine the DNA from patients with possible mutations in the genes. A number of known genetic diseases are now under investigation; however, the vast array of genes that code for

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products important for the normal functioning of the body have hardly been touched.

In addition, large quantities of highly specific antibodies are now being produced in the laboratories through a technology called hybridoma cell fusion. This process results in highly purified monoclonal antibodies that can be used to develop specific vaccines, diagnostic tests, and treatments for many diseases. One such application involves the use of monoclonal antibodies to target the delivery of toxic medication so as to destroy tumor tissue without inadvertently damaging normal tissue. The development of hybridoma technology has influenced not only immunology but continues to be utilized in almost every field of biology.

Until a few short decades ago scientists had only a fragmentary knowledge of the immune system and the mechanisms responsible for its action. This situation is rapidly changing. Scientists have discovered genetic mechanisms that control the immune response to such invaders as cancer cells, transplanted organs, and environmental substances that cause allergies. The genes that regulate these immune responses are called the major histocompatibility complex (MHC). Knowledge of clinical association between MHC and conditions such as juvenile-onset diabetes, certain kinds of arthritis, Alzheimer disease, chronic hepatitis, and myasthenia gravis may lead to better techniques for organ and tissue transplantation.

An especially promising and expanding area is research in neurobiology. New knowledge and techniques from molecular biology are being woven into the fabric of neuroscience, and new methods and instrumentation are permitting safe measurement of an increasingly broad range of anatomic, biochemical, metabolic, and physiological factors in humans. It has been suggested that we are on the threshold of both fundamental insights as to how the brain works and developing treatments for most of the devasting diseases affecting the human nervous system. For example, investigators are finding more and more substances that have profound effects on the nervous system--endogenous neurotransmitters and neurohormones, as well as many externally applied pharmacological substances. They act at "receptor sites" in many locations within brain or nerve tissue. Another exciting area in neurobiology is the study of the body's natural painkillers--the endorphins and other opiate-like substances--which will provide fuller understanding of the mechanisms of brain function, the cause of substance abuse or drug addiction, and the treatment of pain. Their discovery has opened a whole new arena of research into psychoactive substances and their specific receptors in the body and brain. We are well on the way to the conquest of illnesses of the mind and mood, such as depression, that have long baffled medical science.

Question: If we were to take advantage of these advances, what magnitude of growth in resources are we talking about?

Answer: While the research opportunities I have just described represent exciting areas of current scientific activity, they comprise only part of a vast network of research ideas and experimental approaches. Continued progress in biomedical research will depend upon support of research across the full spectrum of disciplines and disease areas. In attempting to estimate the level of resources required to maintain the momentum of this system of scientific

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inquiry over the long run, one must necessarily define "resources" to include at the very least: (a) the support for investigator-initiated, research project grants which represent the wellspring of new knowledge; (b) the provision of a cadre of trained investigators; (c) the support of multidisciplinary centers which provide a focus for translating the results of research into medical practice; (d) the conduct of clinical trials to assess the safety and efficacy of new clinical developments; (e) the upgrading and maintenance of the instruments and research facilities required to carry on modern biomedical research; (f) the development and support of systems for the dissemination of scientific information; and (g) the maintenance of a strong intramural research program at the NIH.

Although it is difficult to achieve consensus on the precise optimal levels of support within and among these activities supported by the NIH, we can, and do, establish relative priorities for the allocation of those resources that can be provided under current fiscal conditions. For instance, we continue to place the highest priority on steady and predictable support for research project grants to individual investigators. Support for this mechanism will continue to be provided at the highest levels possible consistent with the need to maintain the operational effectiveness of the other support mechanisms and within limits that are realistic in view of the economic climate.

Question: What percentage of growth in resources would be necessary to take full advantage of these discoveries over the next 5 years?

Answer: I believe a reasonable goal might be to fund competing research project grants at levels of 45 to 50 percent of approved applications, a point at which at least a significant part of potentially valuable science would be supported.

A complementary goal would be to fund the training of researchers at levels close to those recommended for the NIH by the National Academy of Sciences. This strategy would also call for continued, steady funding of the other NIH mechanisms to avoid imbalances. In addition, appropriate sums would be required to address the levels of need for replacing obsolete research instrumentation and deteriorating research facilities.

SETTING RESEARCH PRIORITIES

Question: If research opportunities expand as rapidly as you and your colleagues are forecasting and Federal support does not expand as rapidly, what is in place to set research priorities for NIH as a whole?

Answer: The NIH has a pluralistic and highly flexible system in place for setting research priorities. The basic framework for this system is formed by the divisions of science inherent in the structure of the NIH categorical Institutes. Each Institute maintains a comprehensive and highly organized process for assigning research priorities within the areas of science that fall under its purview. While these systems vary from Institute to Institute, they share many common attributes. For instance, each Institute places great reliance on the NIH peer review system for assessing the scientific quality of individual research proposals, for providing indica-

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tions of the broad directions in which science is proceeding (as perceived by the community of scientists it serves) and for providing policy guidance concerning the relevance of research grant applications to the specific program needs of the Institute. The assessments of scientific merit and research developments are provided by study sections and other initial review groups; advice on program relevance of applications and matters of broad policy are provided by national advisory councils.

In setting overall priorities the Institutes must meld scientific considerations with broader policy considerations. To accomplish this, for instance, an Institute weighs: (a) the public health importance of a disease (as measured by mortality and morbidity rates and estimates of the social and economic burden of disease); (b) the state of knowledge in areas of science underlying the various diseases; (c) the availability of trained manpower, facilities, and equipment to mount major initiatives; (d) the views of various constituency groups; and (e) the thrust of congressional mandates and special directives.

Collectively, the priorities established by the Institutes form the basic NIH research thrust. This aggregate plan, however, may require modification to accommodate special needs that may arise at the overall NIH level in response to special congressional mandates, Administration initiatives, or urgent public health problems. The Director, NIH, is responsible in such situations for establishing the research priorities for the agency.

In describing this system of priority setting at NIH, I do not wish to imply that this is a simple or straightforward process. In fact, it is a tremendously complex process with a myriad of conceptual and technical considerations at every stage.

Question: What criteria are used to set short-term research priorities?

Answer: In general, the criteria used in setting short-term priorities are similar to those used in setting longer-term priorities; however, the relative emphasis placed on some of these criteria may vary. For instance, these decisions are influenced by: the importance of the health problem to be addressed; the adequacy of the scientific base of knowledge in underlying areas; the probability of success; the estimated costs of the undertaking (both near-term and throughout the project); and the importance of the undertaking as expressed by the Congress, the Administration, and relevant constituency groups.

In assigning a high priority to a short-term goal it is all too easy to be swayed by a high level of concern in special constituencies or to be prompted largely by the overall public health importance of a disease. However, the probability of intervening with any measurable degree of success is often dependent wholly on the adequacy of the knowledge base from which that initiative is launched. Recently, for instance, we have witnessed, in the case of AIDS, an example where this fortunate coincidence of public health need and scientific base has occurred. As a result, we have been able to mount a vigorous program to identify the causative agent and develop screening procedures for its detection in the blood. We are now proceeding with efforts to develop drugs for the treatment of this disease and a vaccine to prevent its occurrence.

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Question: Who is involved in setting these priorities?

Answer: In setting research priorities, the NIH gives consideration to the concerns and wishes of the public, expressed directly and through congressional and Executive Branch actions. Authorizing legislation, mandates, directives, and appropriations all influence our research planning and the conduct of our programs. A few examples of congressional and Administration actions that set our course are: concern for providing greater support to broad areas of research; mandates and directives to allocate a proportion of resources to a particular disease area; directions for long-range plans; changes in research training legislation; proposals for small business set-asides; and establishment of commissions and task forces to provide advice in guiding resource allocations.

Additionally, an important part of the priority-setting process involves the views of professional societies and voluntary health organizations, the biomedical research community, and the general public. These views are sought through a variety of means, ranging from structured activities such as National Advisory Councils, special groups or task forces or commissions to consider specific research areas or health problems, to less structured individual interaction with representatives of such groups.

Finally, the laboratory scientists have a great influence on priority setting in research through their direct participation in a myriad of study sections, training committees, ad hoc panels, and national advisory councils.

Question: To what extent do these priorities reflect the public health impact of various diseases?

Answer: As I indicated earlier, one criterion used by the NIH in weighing the relative importance of a disease is its impact on public health. Various measures of that impact are considered and weighed differently for different types of disease. For instance, for some diseases, notably cancer, cardiovascular, and infectious diseases, the impact on national and international health is of such dimensions as to warrant high priority. Other diseases, however, may receive high priority because they provide unique research opportunities despite their relatively low prevalence or limited geographic distribution. These comparatively rare diseases may have well-defined metabolic or genetic characteristics that make it possible to study underlying mechanisms that also occur in more prevalent diseases but are masked by complicating changes. An interesting example is Huntington's disease, which is a genetic disorder of low prevalence in the United States. However, the National Institute of Neurological and Communicative Disorders and Stroke has given priority to a study of this disorder because it provides an opportunity to study an inherited disease with neurologic manifestations that are similar to those of the more prevalent Parkinson's disease.

I should also mention that the use of assessments of the burden of disease in decision-making about research priorities is complicated because not all factors are quantifiable. It is difficult to compare the burdens of acute vs. chronic diseases; of pediatric vs. geriatric disorders; or of prevalent diseases with low morbidity and mortality vs. relatively rare disease of high morbidity and mortality. Similar difficulties arise when attempting to compare

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the burden of diseases affecting different age groups where loss of earnings during productive years must be considered, as well as the direct costs of the illness.

For these reasons, the data, even when unequivocal, are more likely to provide clues than definitive answers to the question of which disease should receive high priority in a research program.

Question: As Director, what influence do you have in setting long-term priorities, and do you feel that your office needs more clout in this area?

Answer: On balance, I do not feel especially constrained in any way from exercising my influence on the long-range goals and priorities of the NIH. Nor do I believe that structural constraints have seriously impeded the ability of the NIH to respond to special research opportunities or public health emergencies. However, as the history of our involvement in AIDS funding demonstrates, greater administrative and program efficiency could probably have been achieved if it had not been necessary to go through the supplemental appropriation process.

In this regard, a recent report by the Institute of Medicine recommended the establishment of a discretionary fund for the Director, NIH, to be used to provide flexibility in meeting emerging needs during the fiscal year. I believe that the authority, direction, and control that currently exists within the NIH Directorship would be strengthened by having such a discretionary budget for use throughout the fiscal year. This type of fund could be used to address both new emerging areas of need and cross-cutting research opportunities.

FULL-TIME-EQUIVALENTS (FTEs)

Question: Your budget proposal for 1986 places NIH full-time-equivalent staff positions at 704 below the 1984 FTE levels, yet your budget has been increased allowing for additional research to begin in your intramural program. It would appear you are doing more research with less personnel--is that true?

Answer: Approximately 330 of the reduction in FTEs will come from the intramural research program. However, with the realignment of positions and selective contracting out for services, we will make every effort to minimize the impact of the FTE reduction on the research being conducted.

Question: I understand that the Clinical Center has staffing problems--that you cannot employ a full-time anesthesiologist, for example. Have you had to curtail clinical research because of lack of patient care staff?

Answer: The Clinical Center was given special consideration in the allocation of the FTE ceiling. To accommodate the reductions, the Clinical Center is employing a variety of ways to improve productivity within the hospital. This includes limited contracting for services now provided by the Clinical Center employees. In the interim, Institutes have adjusted admission to a level that allows the hospital to continue providing safe, high quality care. In regard to the employment of a full-time anesthesiologist, the problem is not FTE ceiling but the salary level we are able to pay.

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Question: Are you providing the full range of patient services?

Answer: Yes; the full range of patient services is provided at the Clinical Center.

FTEs - POSSIBLE SOLUTION

Question: Dr. Wyngaarden, have you negotiated directly with OMB concerning the FTE levels?

Answer: Generally speaking the NIH does not negotiate directly with OMB. Rather, information is exchanged through the Public Health Service and the Office of the Secretary (OS). The OS did discuss NIH's FTE levels with OMB during the preparation of the budget.

Question: I understand that students, trainees, and visiting scientists are counted as part of your FTE level. How many FTE positions does this category occupy?

Answer: In FY 1984 the NIH used approximately 1,390 FTEs in these categories: 300 FTEs for the Visiting Scientist and Visiting Associate Program; about 930 FTEs for all the Staff Fellows Programs, including Medical/Dental Staff Fellows; and about 160 FTEs for the Summer Program (students). With the exception of the Summer Program, which has been eliminated in FY 1985, we expect to use about 1,200 FTEs this year for these categories of employment.

Question: If these positions were removed from the FTE count and you were then able to fill needed staff positions, would your present level of funding be able to absorb the additional cost?

Answer: If these personnel did not count against the NIH FTE ceiling we would have sufficient funds to hire a small number of additional staff.

Question: Please tell us, for the record, the ways in which these additional positions would be utilized.

Answer: Some examples of how NIH would use additional FTEs include: scientific and technical support for the intramural research program; support services for the intramural research program, particularly the Clinical Center; and scientific and administrative management of the extramural research program.

LOSS OF PHYSICIAN PERSONNEL

Question: I understand that OMB disagrees with the NIH's position on the Physician Comparability Allowance at the NIH Clinical Center. Has this caused the loss in hiring of new physician researchers and/or the loss of present physician researchers? Please provide for the record a description and history of the comparability allowance and why the Administration believes it is no longer necessary.

Answer: The Physicians comparability Allowance Program (PCA) was established by an act of Congress (Public Law 95-603) to provide special allowances to certain physicians employed by the United States in order to enhance the

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recruitment and retention of such physicians. The PCA plan within the Department of Health and Human Services became effective in September 1979. The PCA amendments Act (P.L. 98-168) extended that legislation through September 30, 1989. In April 1984, the Office of Management and Budget directed that agencies wishing to make new or renewal agreements with physicians, submit new or updated plans for OMB review and approval. The HHS PCA plan was approved by the OMB through December 31, 1986. Extension beyond that point will be based on a report detailing the plan's utilization. Now that the OMB has approved the HHS plan there is no longer a problem with regard to the Physician Comparability Allowance Program.

The number of physicians who received comparability pay for the Public Health Service totaled 603 in FY 1985 and the amount paid was $5,031,030. A breakout of these payments by agency is as follows:

Physicians Comparability Allowance
Annual Costs by Agency

Agency	Number	Total Allowance
OASH	6	$ 55,000
HRSA	67	559,700
CDC	19	155,500
Region	4	35,000
FDA	111	966,500
ADAMHA	184	1,426,030
NIH	212	1,833,300
PHS Total	603	5,031,030

CENTERS

Question: I understand that the team approach to research is enhanced by the creation of a research center. Why are you proposing a reduction of 37 centers in the 1985-1986 budgets?

Answer: The rationale for multiyear funding of research project grants in 1985 was extended to research centers. In its efforts to reduce Federal expenditures in 1986 and at the same time maintain a stabilized research centers program, the Administration has proposed that 500 centers be funded in 1985, and that 45 of these be provided with 2 years' support. The level of 500 centers represent a reduction of 33 from the 1985 appropriation. In 1986 there would again be 500 active centers as a result of multiyear funding some centers in 1985.

Question: I understand that biotechnology centers are necessary to maintain this nation's leadership in this area. Why are you

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proposing to reduce by 25 the number of biotechnology centers in 1986?

Answer: Under the 1986 request, the Division of Research Resources would support 51 biotechnology research centers: 37 centers with 1986 funds and 14 centers with 1985 funds as a result of the multiyear funding policy. This total is the same number supported in 1985 current estimate, and is a reduction of 11 from the 1985 appropriation. In order to effect economies in 1986 and at the same time maintain a stabilized program for the biotechnology research centers, it was necessary to apply the multiyear funding concept to research centers as it was applied to research project grants. The level of 51 centers in both 1985 and 1986 is an increase of 4 centers over the 1984 level.

TRAINING

Question: Your 1986 budget proposes to support 9,891 research trainees. The scientific community has forecast a major expansion in knowledge and research opportunities that may well continue into the 21st century. Are we training enough scientists to meet this growth?

Answer: The 1986 budget request provides for approximately 9,900 training positions. This number should provide for continuity of a critical mass of trainees necessary to conduct future research to improve the health of the nation.

Question: Once trained, how many of these scientists will be successful in competing for grant support?

Answer: Approximately 65 percent of NIH-supported predoctoral trainees become engaged in Federally sponsored research--50 percent supported by NIH and 15 percent in some other Federally sponsored activity.

A study of the success rate of postdoctoral individuals who have received NIH postdoctoral training and later applied for research grants show that approximately 50 percent of Ph.D.s trained on institutional research training grants apply for, and approximately 40 percent receive, research project awards. Approximately 20 percent of M.D.s trained on institutional research training grants apply for, and approximately 10 percent receive, research project awards. Approximately 60 percent of postdoctoral Ph.D. individual fellowship holders apply for research projects and approximately 45 percent receive awards. Approximately 50 percent of M.D.s receiving research training on individual fellowships apply for research project grants and approximately 30 percent receive them.

It must be emphasized that, while receipt of the investigator initiated research project award is a good measure of participation in research, it is not the sole measure, as many trainees participate as co-investigators or subproject investigators on other types of NIH award mechanisms. Others receive research support from private agencies and institutional funds.

Question: Given retirement, drop-outs and the like, how many biomedical scientists are being added each year?

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Answer: The 1983 Institute of Medicine report on the Nation's Needs for Biomedical and Behavioral Research Personnel developed the following estimates for annual faculty replacements: approximately 2,590 new clinical faculty are needed annually--390 to fill vacancies resulting from death and retirement, approximately 500 for expanded programs, and 1,700 to replace those leaving for other reasons. For Ph.D. faculty, approximately 1,900 new hires are needed annually--370 to fill vacancies resulting from death and retirement, 430 for expanded programs, and 1,100 to replace those leaving the academic setting--many of whom will continue in research.

Question: What happens to the excellent young scientist who is frustrated by the 1 in 3 success ratio for grant funding?

Answer: Of the young scientists who, with research grant support, would normally expect to enter or continue a productive academic career, a portion will accept industrial research positions and some will enter administration. Others will remain in the research world at something less than the principal investigator level, serving as postdoctoral fellows or mature research associates. Other young investigators will accept academic appointments at the smaller universities and colleges that do not have substantial research resources. The survey of earned doctorates conducted by the National Academy of Sciences indicates that there is a very low number of people trained in biomedical and behavioral research who will leave the field entirely.

Question: Given the grant funding ratio, should we re-evaluate the training program?

Answer: The Congress designated the Institute of Medicine as the body to conduct a continuing study of National Needs for Biomedical and Behavioral Research Personnel. In the biennial report, the needs for biomedical and behavioral research personnel are developed and reported in a way that takes into account the requirements of academia and industry as well as the opportunities for research and scientific advancement. The next report will be available in September 1985.

RESEARCH CAREER PROGRAMS

Question: I understand research career programs are designed to provide young investigators who have shown unusual promise an opportunity to achieve higher productivity at an earlier stage in their careers. Why are you proposing a reduction in this program?

Answer: While the research career programs are indeed important, it was necessary within the 1986 budget level to make some minor reductions in several areas of support.

DETERIORATED FACILITIES

Question: Dr. Wyngaarden, you have expressed concern that many of our universities have physical facilities, used for research, that are old and in serious disrepair, and that extensive rehabilitation or replacement is necessary. What assessments have been made concerning this problem, and how current are the data?

Answer: With one exception, no comprehensive assessments of the

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condition of the nation's research facilities have been conducted since 1969. The exception is a very recently completed survey of cancer research facilities, which has revealed the need for investment in cancer-related research facilities of $580 million by 1990. Several projections of need in other research facilities have been based on reports by small numbers of individual institutions in the research community, but such reports do not serve as adequate evidence.

We believe there is an absence of sound, systematically gathered factual information, and the NIH has therefore proposed and is now awaiting OMB clearance to conduct a national survey of the research facilities of academic institutions and independent research institutes and hospitals. The aim is to establish a record of the age and condition of existing facilities, and to determine whether and how facilites needs are currently being met. From these data we would project an estimate of need.

Question: To what extent is the progress of research being impeded by inadequate or obsolete facilities?

Answer: This is one of the questions NIH plans to address in its proposed survey of research facilities. We have already learned from a national survey of academic biological and biomedical science departments that over half of those surveyed reported that there are important subject areas that cannot be addressed because of the lack of necessary instrumentation. We feel it is important to determine the extent to which inadequate facilities also contribute to this problem.

Question: Can you present this committee with a proposal as to how this problem can be solved?

Answer: Once we obtain factual information about the nature and extent of the problem we will be able to formulate a rational approach to its solution.

INADEQUATE INSTRUMENTATION

Question: We have also been told that instrumentation at our universities may be inadequate, and in some institutions, obsolete. Is this true, and if so, how extensive is this problem?

Answer: A survey was recently conducted by Westat, Inc., to determine the research instrumentation needs in the biological and medical sciences. The survey sampled 43 graduate schools and 24 medical schools and arrived at the following results:

- The 1983 national stock of academic research equipment in the biological sciences and departments of medicine is estimated to have an aggregate original cost of $555 million; the replacement cost (in 1982 constant dollars) is estimated at $863 million.

- Of the instruments in the 1983 national stock, 44 percent were 5 years old or less; 29 percent were 6 to 10 years old; and 27 percent were over 10 years old.

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- o Only 18 percent of the instruments in the 1983 national stock were classified as state-of-the-art.

- o About 15 to 16 percent of the department heads characterized the adequacy of their research equipment as "excellent."

- o Nearly 60 percent of the department heads reported that there are important subject areas that cannot be addressed because of lack of necessary equipment.

- o About half the department heads described existing facilities for maintenance and repair in instrumentation as either insufficient or nonexistent.

- o According to the department heads, the types of research equipment most urgently needed were predominantly below $75,000.

In our view, the results of the survey indicate that much of the needed research instrumentation at universities and research institutions is inadequate, obsolete, or nonexistent.

Question: How current are your data?

Answer: The survey by Westat of academic research equipment needs in the biological and medical sciences was conducted during calendar year 1984. It reports on instruments in the national stock in calendar year 1983. Questions regarding equipment expenditures covered those actually made in 1983 and anticipated for 1984.

Question: Can't these needs be met by research project grants?

Answer: Individual research project grant awards do provide for the purchase of equipment needed for that single research project. In 1984, 2.9 percent of research project grant funds were awarded in the equipment category.

More expensive instrumentation whose price places it beyond the reach of a single investigator is provided by the shared instrumentation program operated by the Division of Research Resources and by supplemental funds for shared instrumentation awarded by the National Institute of General Medical Sciences.

The Instrumentation Review Committee, an ad hoc committee of senior NIH staff, is currently reviewing the adequacy of these mechanisms in meeting the needs for research instrumentation for NIH extramural scientists.

Question: Do you have a proposal to deal with these problems?

Answer: NIH currently has several initiatives designed to address these instrumentation problems. Within the Division of Research Resources (DRR), there is the Biomedical Research Support-Shared Instrumentation Grant (SIG) Program, the Biomedical Research Technology (BRT) Program, and an instrumentation initiative at Minority Biomedical Research Support (MBRS) institutions.

Through the SIG program, DRR provides support for the acquisition of large-scale, sophisticated, state-of-the-art instru-

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mentation in the $100,000 to $300,000 cost range, which is utilized by groups of PHS-funded investigators on a shared-use basis. In 1986, the budget request for the SIG program is $31.8 million, which will enable the DRR to support between 145 and 170 awards.

The BRT program will continue to address the instrumentation needs of the biomedical research community by providing advanced instrumentation at biomedical research technology centers, by supporting research on instrument development or new techniques, and by supporting training in the application of research technologies using high technology instrumentation. The 1986 budget request for this program is $18.5 million.

Within the MBRS program, $1.0 million is available in 1986 to make supplemental awards to MBRS institutions to enhance the research environments of these minority institutions by providing much needed research instrumentation.

The National Institute of General Medical Sciences (NIGMS) also supports a smaller Shared Instrumentation Grant program (about $278,000 in 1986) aimed at improving the analytical instruments used by the Institute's grantees, thus contributing to the vitality and success of the fundamental studies supported by the NIGMS.

In addition, each of the research Institutes makes awards in the equipment category of research project grants for the purchase of smaller scale instrumentation that is needed for the research activities supported by the grant. Historically, the average amount awarded for equipment has been approximately 2.9 percent of the total amount of the research project grant.

NIH plans to continue its emphasis on providing new research instrumentation and replacing obsolete instrumentation to the biomedical research community. Instrumentation awards in 1986 will remain at approximately the same level of support as in 1985.

ALZHEIMER DISEASE

Question: You indicate some possible progress in Alzheimer disease research that may have important implications for improved diagnosis and treatment. How much are you planning to spend in 1986 on Alzheimer disease?

Answer: We plan to spend $46.3 million in 1985 and $40.6 million in 1986. From a program level perspective, the NIH plans to spend approximately $43.4 million for research on Alzheimer disease in 1986 compared to $42.5 million in 1985.

Question: Congress has directed the development of 10 Alzheimer Disease Centers. How many are now in operation?

Answer: There are currently five Alzheimer Disease Centers in operation, which were awarded in 1984. We plan to award an additional three centers in 1985 for a total of eight in operation by the end of fiscal 1985. In 1986, two more will be added.

Question: If Congress reaffirms its 1985 appropriation, will you be able to get the rest started by the end of 1985?

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Answer: We have a sufficient pool of applications from which to draw so that if the 1985 appropriation is reaffirmed by Congress, we would be able to start the remaining centers by the end of fiscal 1985.

Question: If not, when do you expect all 10 centers to be operating?

Answer: All 10 Alzheimer Disease Centers will be operational in 1986, regardless of the 1985 funding policy that is ultimately implemented.

AIDS

Question: The 1985 appropriation for AIDS was about $96 million. The NIH received $61 million of that amount. How will OMB's Directive limiting the number of grants to 5,000 affect the AIDS research effort?

Answer: Now that the etiologic agent of AIDS is known and the genetic sequence has been found, our emphasis is shifting from basic, grant-supported research to more developmental and applied efforts. Therefore, the OMB directive on grant limitation is expected to have no affect on the AIDS research effort.

Question: Will that Directive cause research funds to be diverted from any other programs? If so, please provide the names of those programs and the amount of funds diverted.

Answer: Although the OMB directive does limit the number of grant and center awards that can be made in 1985, the funding amounts in the extramural mechanisms have remained unchanged. Therefore, research funds have not been diverted because of the directive.

Question: Dr. DeVita, the Director of the National Cancer Institute, was recently quoted as saying that he was expected to reprogram $15 million this year for AIDS research. Is that correct? Which fiscal year are you talking about?

Answer: In fiscal year 1985, the NCI originally anticipated a need to redirect approximately $5.9 million from other areas in order to meet the requirements for AIDS research. Currently, NCI estimates that the amount that will be redirected to AIDS research is $3.9 million.

Question: He also is quoted as saying that he has been required to spend more than $50 million on AIDS since 1983 but has received only $5 million in supplemental funds. Is that correct?

Answer: NCI AIDS obligations have been as follows:

1982.....	$ 2,406,000
1983.....	9,790,000
1984.....	16,588,000
1985 est.....	24,851,000
	53,635,000

In fiscal year 1983, NCI received a supplemental of $3.3 million; in 1984, the Congress provided a supplemental of $2 million,

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for a total of $5.3 million. From 1982 through the 1985 estimate, then, NCI will have expended $53.6 million for AIDS research, of which $5.3 million was provided through supplemental appropriations. It is normal that throughout the annual budget cycle NIH reevaluates competing priorities and emerging research opportunities and makes budget allocations based on a number of considerations within total resource levels that are provided.

Question: How many dollars had to be reprogrammed in 1984 and 1985 within the National Institutes of Health for AIDS research?

Answer: We estimate that $11 million will be redirected for AIDS research in 1985.

Question: Why didn't a supplemental request reach Congress for 1984? Can we expect one in 1985?

Answer: As with any relatively new and complex public program, development of a firm estimate of resource requirements 9 to 12 months in advance is difficult. Because of the dynamic nature of the AIDS effort--discovery of causative agent, development of blood test, work toward development of vaccine, preparation of control, etc.--the formulation of estimates of resource requirements has been difficult. To assure that the PHS agencies keep up with the current state of the overall AIDS effort, we are periodically asked to reassess our AIDS resource requirements.

During fiscal year 1984, shortly after the discovery of the causative agent, the PHS agencies identified additional AIDS needs for the remainder of 1984 and for 1985 as well. PHS made those needs known to the Secretary. While the request was still being considered by the Department, the Congress enacted a supplemental for AIDS research for fiscal 1984. Therefore the request was not sent to the Congress. With regard to 1985, the PHS request for additional AIDS resources was submitted to the Secretary during the process of congressional consideration of the 1985 budget. Congress added substantial funds (approximately $1 billion) to the President's request for PHS. The Secretary responded to the PHS request for additional AIDS resources by asking that PHS make an assessment of the 1985 Congressional action. She stated that, if additional needs for AIDS resources were identified, the Department would take appropriate action. PHS made the assessment and reported to the Secretary and the Appropriations Committee that the 1985 appropriations were adequate to meet the needs identified by PHS at that time.

During the several months that have elapsed since then, we have witnessed several scientific breakthroughs--such as the coding of genetic sequence and the development of a blood test. At the request of the Assistant Secretary for Health, we have undertaken a very recent reassessment of AIDS research findings and areas of possible exploration. The Secretary has promised to keep the Congress informed of any changes in resource needs.

ANIMALS

Question: Dr. Wyngaarden, I have been receiving a great deal of mail concerning the use and care of animals in research. How can we be sure that abuse of animals used for research does not occur?

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Answer: U.S. Public Health Service (PHS) policy requires awardee institutions to establish and maintain proper measures to ensure the appropriate care and use of all animals involved in research, research training, and biological testing activities.

All awardee institutions are required to comply by submitting a written assurance acceptable to the PHS setting forth conformance with this policy. The assurance implements regulations in the Animal Welfare Act of 1966 as amended, endorses U.S. Government Principles for the Care and Use of Vertebrate Animals, and follows the recommendations in the current edition of the Guide for the Care and Use of Laboratory Animals. These highly respected guidelines were developed and have been refined in consultation with scientists, veterinarians, and the public over the last 20 years. Each institution must assure that its program and facilities are accredited by the American Association for Accreditation of Laboratory Animal Care or evaluated by the Institution itself.

The new PHS policy will require awardee institutions: 1) to designate a single official accountable for the proper conduct of the animal care and use program; 2) to designate a veterinarian responsible for supervising the care, use, housing, and feeding of all animals; and 3) to appoint an animal care committee to oversee the institution's animal care program. This committee must review research activities and animal research protocols, ensuring that the procedures used will avoid or minimize unnecessary discomfort, distress, and pain to the animals.

Each institution is subject to review at any time by PHS staff and advisors. A site visit may be conducted to assess the adequacy of the institution's compliance with the policy or to evaluate allegations of noncompliance with the policy. Each allegation or complaint of misconduct involving animals is investigated. In rare instances, it may be necessary to revoke an institution's assurance or suspend and terminate an award.

Each institution is monitored by the U.S. Department of Agriculture (USDA) under a provision of the Animal Welfare Act. USDA representatives make periodic, unannounced inspections to ensure compliance with standards for housing, feeding and watering, cleanliness, ventilation, and veterinary medical care. The law permits the assessment of penalties for violations, including fines and/or the closing of the facility.

NIH cooperates with the USDA and Food and Drug Administration in accordance with a Memorandum of Understanding. These agencies share information they receive in connection with their inspection programs. Serious and continuing noncompliance with Government policies allows the agencies to pool efforts in addressing common problems.

Question: Are research protocols examined to ensure the appropriate use of animals?

Answer: Before beginning a research project, the institutional investigator develops a proposal describing the purpose, objectives, and experimental design, including the selection of an appropriate animal model. The proposal is then subjected to repeated independent examination throughout the NIH review process:

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- Before leaving the awardee institution, the principal research administrators, often with the advice of institutional review groups and animal care committees with at least one veterinarian, must approve the application or proposal. Important considerations in the institutional review include the choice of the animal model, the number of animals to be used, and the description of experimental procedures. The institution must determine that the planned research can be conducted within the assurances given to the NIH regarding the proper care and use of laboratory animals.

- When the application or proposal reaches the NIH, study sections or other initial evaluation groups composed of non-Federal scientists review the project for scientific merit. They are also required to assess the appropriateness of the species of animals used, the numbers of animals used, and the experimental procedures intended to safeguard animal subjects from unnecessary pain or distress.

- If any problems or questions regarding the proposed use of animals are identified, the application or proposal is given further consideration and judgment by NIH Bureau, Institute, or Division staffs and/or Councils or Boards, or may be directed to the NIH Office for the Protection from Research Risks. All questions or concerns about the welfare of laboratory animals must be resolved to the satisfaction of the NIH before an award can be made.

Question: What can you tell us about the value of computer simulation as replacement for research using animals?

Answer: Ethical and economic arguments have been raised that investigators should develop nonanimal models for biomedical research and substitute them for animal models. To evaluate this approach to research, the NIH Division of Research Resources funded a series of workshops on the subject of "Selecting Models for Biomedical Research." Sponsored by the National Academy of Sciences, the workshops brought together scientists from many disciplines to discuss the use of cell and tissue culture methods, nonmammalian organisms, mathematical modeling, and computer simulation in biomedical research. The workshops also served to make more scientists aware of various models that might now or in the future be available for particular kinds of research activities.

Since the ultimate objective of using models in biomedical research is to understand the human organism, the participants were asked to review the relevance and limitations of various models, including mathematical and computer models, to the biomedical research sponsored by the NIH. The scientists described research activities using computer models developed for a number of bodily functions. Computer simulations with hundreds of variables have led to the development of exciting new concepts and discoveries in such fields as hypertension, carbohydrate metabolism, and drug administration.

These experts cautioned, however, that although these models have sometimes guided investigators in the design and interpretation of experimental programs, computer stimulation cannot replace the use of vertebrate animals. Indeed, the development of new constructs

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and theories may generate, at least transiently, a need for using more animals in defining the problems and validating the experiments.

Question: Congressman Torricelli has introduced a bill to prevent duplication of research involving live animals. I understand that a certain amount of duplication is necessary to verify research finding. How can we be sure that such duplication is not excessive?

Answer: Research scientists may appear at times to be duplicating their efforts and using animals unnecessarily in their search for new knowledge about diseases that affect humans. However, appropriate replication of research projects is a critical part of the scientific process because it provides for rigorous testing of hypotheses and the formulation of conclusions that carry a high degree of conviction. Small differences in experimental conditions may produce significant variations in the responses of living systems. Novel findings are intentionally subjected to intensive validation so that researchers throughout the world may draw upon them for their own investigations. Laymen not familiar with the research process may erroneously consider such activities as redundant or duplicative.

To avoid unnecessary duplication, the NIH depends upon its scientific peer review system. Because of the magnitude, diversity, and complexity of the NIH research mission and the desire to obtain the best advice possible, the NIH draws for assistance on the national pool of scientists actually engaged in research. Nearly 2,000 non-Federal scientists assist the NIH in the selection of the most meritorious research projects designed to implement biomedical research programs of the highest quality. The NIH peer review system consists of two sequential levels of review, both having statutory bases. The first review is performed by scientific review groups established along lines of scientific disciplines; the second is performed by a Council or Board for each Bureau, Institute, or Division that supports extramural research.

The current review system is effective in assuring that unnecessary duplication of research does not occur. All applications or proposals for research support from PHS agencies must include a bibliography which lists relevant literature. This listing must be sufficiently comprehensive to demonstrate that the investigator is aware of current and past research in the area, has used that information as a basis for the proposed studies, and is not needlessly duplicating previous work. In addition to evaluating relevant existing knowledge, the investigator must describe the information to be gained by the proposed project. All this information is evaluated by reviewers. If vertebrate animals are to be involved in a research protocol, reviewers must assess specifically the need to use these animals. After the initial scientific review, National Advisory Councils or Boards, composed of non-Federal scientists and nonscientists who represent the public, perform a second review. The scientific staff of the funding agency also participate in this process.

The limited availability of research funds also serves as a check on unnecessary research. The NIH, for example, is able to fund only about one-third of all research proposals judged

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worthy of support. Therefore, funds cannot be awarded for studies that will not add significantly to the body of biomedical knowledge.

As the principal resource for biomedical information from published literature, the NIH's National Library of Medicine (NLM) is mandated to acquire and preserve medical literature and to promote its availability through catalogs and current bibliographies. To facilitate access to its databases, NLM operates the computerized bibliographic information service known as MEDLARS. These online services are available at more than 2,000 medical institutions throughout the nation. Further, the NLM supports seven regional medical libraries and many more resource libraries. Thus, the effectiveness of the current systems in disseminating biomedical information helps preclude unnecessary duplication of research.

INTRAMURAL BUDGET

Question: For 1986 you are requesting a $32.5 million reduction from current services levels in the intramural programs. Your justifications assume a 5-percent pay reduction and savings in administrative costs. How do you plan to achieve those savings without affecting programs?

Answer: The request level for intramural research represents a reduction of $48.8 million from the current services level, of which $32.5 million relates to reductions in administrative costs and the 5-percent salary reduction. We will be reviewing the intramural program very carefully in order to achieve these reductions with minimal impact on the research program. The 5-percent salary reduction applies across the board to all staff. The remainder of the reduction below current services, about $16.3 million, will require absorbing the costs of inflation in supplies and equipment across all components of the intramural research program.

INDIRECT COSTS

Question: In 1986 you are proposing a freeze of indirect costs at the 1985 level. Do the indirect costs paid to the universities by the NIH reimburse the university for the total cost of maintaining the NIH-sponsored research programs?

Answer: A university's Indirect Cost Negotiation Agreement contains rates developed in accordance with Office of Management and Budget Circular No. A-21, "Cost Principles for Educational Institutions." All of a university's costs are not allowable under A-21, such as costs of fund raising, investment management, and certain interest charges. Further, since 1966 the Congress has required all research grantees of the Department of Health and Human Services to share in the total cost of research, and some have opted to meet that requirement by not claiming all the indirect costs to which they are entitled through the application of negotiated rates. This cost-sharing requirement is contained in Section 202 of the Department of Health and Human Services Appropriations Act for fiscal year 1985.

PROGRAM BASE

Question: In 1985 Congress added $583 million to the NIH request mandating increases in extramural research training, intramural programs, and career development just to mention a few items.

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Congressional intent was to bring the operating and program levels to a more realistic base--given the advances in science that have occurred over the past decade. How many would have to be added to the $5.1 billion 1985 level in 1986 to maintain that increased program base?

Answer: In order to maintain the 1985 program base in 1986, about $465 million would have to be added to the 1985 appropriation level, for a total budget of $5,616 million.

Question: Where in your opinion can savings be effected without diminishing the program base?

Answer: Because of the high priority we place on investigator-initiated research, the major portion of our budget is for research project grants. As you know, indirect costs on these grants have been growing steadily as a percentage of the research dollar. I believe that some savings could be achieved by tightening up some of the categories of indirect costs for which reimbursement is currently permitted. The NIH has been working with the Office of Science and Technology Policy in its study of options to find a long-term solution for containing the growth of indirect costs in research grants.

Within the intramural research and research management and support activities, our search for savings is an ongoing process. Our efforts in these areas have focused on automated data processing and consolidation of functions. The review process for research grants, for example, has been substantially streamlined in recent years as a result of automation. So have our accounting and procurement functions, to mention another example. We continue to seek ways to cut administrative costs; however, the potential savings in these areas are of much smaller magnitude that those that could be achieved from a fundamental change in the indirect cost policy.

PREVENTION CONFERENCE

Question: Dr. Wyngaarden, we understand that your office is co-sponsoring, along with the Office of the Assistant Secretary for Health (OASH), a conference next year on "Research in Prevention." Just exactly what is the purpose of this meeting and what do you hope to get out of it?

Answer: The meeting is intended to provide a forum for increased scientific awareness of the state-of-the-art that will enable investigators to prepare and submit new and innovative approaches to furthering the science of disease prevention. In addition to OASH, the NIH is working cooperatively with the Association of Schools of Public Health, the American College of Preventive Medicine, and the Association of Teachers of Preventive Medicine in planning for this important conference.

Question: Can you tell us more about what NIH is doing in behavior-oriented prevention research which addresses risk factors?

Answer: The NIH conducts and supports numerous studies relating to behavior and risk factors that are important in the prevention of disease. Examples of such studies include the following:

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The NCI is involved in studies relating diet and nutrition to the incidence of various types of cancer; many of these will study behavioral modification as a key element in carrying out the sometimes severe changes in dietary practices that are necessary. Other NCI studies pertaining to risk factors involve epidemiologic research aimed at elucidating occupational hazards and the risk for certain types of cancer.

In the smoking and health area, many Institutes are involved in significant behavioral studies on risk factors: the NCI in the areas of lung, buccal cavity, espohageal, bladder, and pancreatic cancer; the NICHD in the areas of prenatal development and adolescent behavior, including the broader issue of risk taking and accident prevention; and the NHLBI in behavior modification where it may reduce risk for coronary and pulmonary diseases.

In related areas, the NIDR funds studies on behavior patterns and risk for caries and periodontal disease. The NIAID is involved in behavior patterns and risk for identified allergies, including asthma, food poisoning, psoriasis, and other conditions. The NEI is funding studies on risk taking in certain occupational settings and incidence of eye injuries, including burns, abrasions, and retinal detachments.

PUBLIC HEALTH EMERGENCY

Question: The Public Health Emergency caused by AIDS has had a tremendous impact on the entire Public Health Service, especially at NIH. Are you satisfied with the NIH's response to this emergency?

Answer: We are really quite proud of the accomplishments of scientists working at and supported by the NIH. I cannot recall another occasion in which so much has been learned in so short a time about an entirely new disease.

Question: What were the major problems caused by this emergency:

Answer: It is not commonly realized that the earliest problem was to determine whether an emergency really existed. In December 1981, when the first scientific papers describing the outbreak were published in the New England Journal of Medicine, an editorial whimsically noted that there were "three papers, 19 patients, and 32 authors." A further period of time had to elapse before nationwide surveillance conducted by CDC made it clear that we were faced with an epidemic--not a self-limited cluster of unusual cases. Until this was accepted, the scientific community was loath to divert major resources and talent from the multitude of other important killer and crippler diseases that afflict our population. Probably the best minds and most well-equipped laboratories were the very ones with the largest ongoing commitments; thus some of the earliest research proposals related to AIDS received by the NIH were of limited scientific merit.

AIDS is extremely unusual among infectious diseases in the length of its incubation period, and in the slow pace of its clinical evolution. As a previously unknown disease, its natural history could not be described at once, and more time had to pass before certain key observations (such as transmission of the disease to

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hemophiliacs in Factor VIII concentrate) could be made. The necessity for the formulation of reasonable scientific hypotheses to flow from observable facts tended to hold the expansion of scientific research to the relatively slow pace of the disease itself.

I believe that these problems, which are a necessary consequence of the nature and natural history of the disease, far outweighed any administrative or budgetary restrictions in retarding the earliest phases of the investigations of AIDS.

Question: How can the response mechanism be improved?

Answer: We have had a number of suggestions for facilitating a more rapid response to a public health emergency through extramural assistance mechanisms. These range from a discretionary fund at the disposal of the Director of NIH to the proposals for an appropriation for public health emergencies contained in legislation introduced into, but not passed by, the last Congress. Each of these would make it possible to provide support quickly in a new area of health research, but each incorporates the companion hazard of fewer safeguards against errors. In my opinion, had either of these mechanisms been in place in 1981-1982, its use would have had at most a marginal effect in forwarding the research on AIDS that ultimately proved to be the most important.

Question: What, in your opinion, can Congress do to improve the response mechanism?

Answer: With the AIDS epidemic as a illustrative example, it appears to me that one of our most important hurdles is reached when scientific leads to a practical method of intervention for either prevention, diagnosis, or treatment of an epidemic disease. Rapid development of that basic knowledge into materials or procedures that can be applied on a large scale is needed. Recently we have seen the responsiveness of private industry to the challenge of producing reagents to test blood for AIDS antibodies by the millions. However, situations may arise where the private sector cannot or will not step in so effectively, and the public sector may have to bear the burden. Such a situation may arise with a lead time that is much shorter than the normal Federal budgeting process; an expedited method by which the Congress could consider and pass on supplementary budget requests could be of considerable value.

SUPPORT OF CREATIVE RESEARCH

Question: While I support the peer review method of judging the value of research proposals submitted to the NIH, there has been some discussion that the scientists that sit on the peer review panels may be overly dependent on "past performance" and "traditional or proven methodologies." If this be true, doesn't this present a disadvantage to the young or innovative investigator?

Answer: It is true that young, innovative investigators would be at a disadvantage if peer review panel scientists depended too much on "past performance" and "traditional or proven methodologies" in evaluating the merits of grant applications. Our experience shows, however, that peer review members do recognize and react favorably to creative and potentially productive new ideas. This observation is supported by the fact that in recent years about

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25 to 30 percent of the principal investigators who competed successfully for individual research project grants are new to the NIH system. In fact, almost half the principal investigators winning new competing awards are new principal investigators. This results in from 8 to 10 percent of total research project grants being awarded to investigators who are new to the system.

Question: How much discretionary power does the institutional leadership have in recognizing and funding creative proposals?

Answer: Institute Directors and their senior program officials have considerable authority to recognize and fund creative grant applications that fall below what otherwise would be priority score cut-off levels in their Institutes. However, the DHHS Office of General Counsel must review any plans to award grants for applications whose priority score points fall more than 50 below the estimated paylines for identified programs. Also, the Institute Directors report to their National Advisory Councils and Boards regarding applications that are funded outside the regular priority order.

Question: To what extent is this discretion used?

Answer: This discretionary authority is applied in only small numbers of applications. After technical review has already identified outstanding innovative applications, and Councils and Boards have recommended funding others because of their high program relevance, relatively little opportunity is left for Institute officials to select additional examples for funding outside customary priority order.

CLINICAL TRIALS

Question: Last year Congress provided NIH with funding for 49 clinical trials. I see these trials functioning in three interrelated areas: They bring research results to the bedside; they provide additional knowledge in the area of disease and disability prevention; and they judge the effectiveness of both new and old therapies. What is the appropriate role for the NIH in these clinical trials?

Answer: With clinical trials, as with all research projects, the NIH must select the most meritorious from among many competing proposals, not all of which can, or should, be supported. Those clinical trials most worthy of NIH's support are those which are technically, methodologically, and ethically sound, and which fulfill one or more of the following criteria:

- o The trial holds promise for making a substantial contribution to the health of the American people.
- o It may well complement basic laboratory and animal research in increasing understanding of the basic biology of the target disease.
- o There is a distinct possibility that its execution will contribute to future improvements in the design, analysis, and interpretation of clinical trials in general.

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Question: Are there only certain types of clinical trials or research that should be supported by the NIH? If so, what are they?

Answer: The NIH has a very broad mandate for performing and supporting clinical research, of which clinical trials are a subset. The previous answer lists major criteria for setting priorities. There are probably only a few classes of studies that the NIH should not consider funding. These might include studies of potentially highly profitable, proprietary products, where the patent holder should himself undertake clinical studies to satisfy FDA's marketing requirements, and clinical trials designed to disprove the usually unsubstantiated claims of advocates of "unconventional" therapies.

Question: What are other sources of support for necessary trials, and is that support sufficient?

Answer: There are principally two other sources of support for needed clinical trials. Industry supports clinical trials of proprietary products in order to collect the data needed to support applications to FDA for approval for marketing of new drugs, biologics, and devices. To a much lesser extent, private nonprofit, voluntary, or philanthropic organizations support clinical trials that are of particular interest to them. The most important gaps in support for clinical trials are in studies of surgical and other procedures that do not involve a specific marketable product, and studies designed to demonstrate ways to decrease health care costs without acceptable sacrifices in health outcomes.

CLINICAL CENTER

Question: I understand that at times bed space at the Clinical Center is inadequate. How is the decision made for research bed space at the Clinical Center?

Answer: The overall assignment of the Clinical Center's patient care units occurred more than 20 years ago and reflected the relative sizes of the clinical programs at that time. Since then, relatively minor adjustments have been made as new Institutes have been brought into the Clinical Center, such as the NEI, NIA, and NIAAA. When adjustment of bed assignments is necessary, the options are discussed by the Medical Board and Scientific Directors, and the final decisions are made by the Director, NIH. Generally, the number of beds assigned to each Institute appears to be adequate to support that Institute's clinical program. There are occasionally short-term problems connected with beds out of service due to renovations. In these types of situations, Institutes often "loan" beds to each other until the crisis is past.

Question: Does the Medical Director of the Clinical Center have input into this decision?

Answer: Yes; the Director of the Clinical Center makes recommendations regarding bed allocations when either permanent or short-term reassignments are necessary.

Question: Is the bed space problem due to lack of physical space or does it have to do with staffing shortages?

Answer: The Clinical Center currently has an adequate total

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number of beds to support the clinical programs of the Institutes. Overall, the Clinical Center has been staffed to support a 70-percent occupancy rate. Problems of "bed shortages" occur when an Institute needs to implement a clinical program that requires a high occupancy rate--say 85 to 90 percent. We have been able to support occupancy rates higher than 70 percent on some units by reallocating staff from units that have a less intense clinical program. However, when an Institute that has had a relatively small clinical program receives a new mandate or recruits a senior investigator with a new emphasis, sufficient resources may not be available to meet the demands of such an Institute for expanded support of its clinical research programs.

Question: Do the staffing shortages occur because of low pay or lack of FTEs?

Answer: We have experienced some difficulty in recruiting and retaining certain categories of technicians with highly specialized skills, such as critical care, heart pump, ultra-sound, and radiology. It is also difficult to retain physicians in certain specialty areas such as radiology. Aside from these problems, affecting a relatively small number of employees, our salary and benefit levels appear to be reasonably competitive with area hospitals.

REHABILITATION

Question: Rehabilitation is an important part of treatment of disease and congenital defects. In fact the interest in rehabilitation research is growing quite rapidly. What emphasis is the NIH placing in this area?

Answer: Research in rehabilitation includes investigations on all types of diagnosis and therapy used to evaluate, replace or restore function, or to prevent the occurrence of deterioration following disease or injury. The use of the word "therapy" emphasizes the fact that no clear boundary separates rehabilitation from treatment. Therefore, it is appropriate that NIH conduct and support rehabilitation research in carrying out its mission to overcome or alleviate the health problems of Americans.

The extent of this commitment is demonstrated by the variety and breadth of research programs concentrating on prevention or treatment of disabilities that are supported by nine of the eleven Institutes and by the Division of Research Resources. These include studies on paraplegia due to head and spinal cord trauma, sensory impairment such as blindness and deafness, cleft palate and other congenital anomalies, osteoporosis and developmental defects of bone and connective tissue, and metabolic and genetic diseases such as diabetes.

In addition to expanding the understanding of disease processes and treatment, NIH conducts research designed to improve the quality of life for disabled persons. These efforts include the development of prosthetic instruments and devices as well as the study of biomaterials of potential use in prosthetic devices, counseling following myocardial infarction, and educational programs directed toward limiting the psychosocial effects of being disabled.

In accord with its role as the principal government agency supporting biomedical research, NIH also participates in a number of

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government-wide groups focusing on the needs of the disabled. Among these are the Interagency Committee on Handicapped Research; the National Institute for Handicapped Research, Department of Education; and the Committee on Hearing and the Committee on Vision of the National Research Council, National Academy of Sciences.

Question: What NIH Institutes are taking the lead in rehabilitation research?

Answer: As noted earlier, nearly every Institute conducts research related to rehabilitation. However, the missions of particular Institutes tend to link them closely to the diagnosis, prevention, and treatment of disabilities resulting from disease or natural processes. For example, about 2 million people, nearly 9 percent of the American population over the age of 65, require some assistance in carrying out the basic activities of daily living such as walking and eating. Therefore, the National Institute on Aging supports research on illness and disability in the elderly including research on cognitive rehabilitation of post-stroke patients and on bladder retraining techniques for patients with urinary incontinence.

The Mental Retardation and Developmental Disabilities Branch of the National Institute on Child Health and Human Development funds research on rehabilitation in two broad areas: medical treatment and education. The goal of these studies is either to prevent retarded development in populations at risk, or to improve functioning in those already diagnosed as retarded.

The National Institute of Neurological and Communicative Disorders and Stroke conducts and supports research and research training that addresses problems virtually all of which relate to handicapping conditions. Two examples are: 1) the neural prosthesis program, which couples investigation of basic electrophysiology of stimulation and neural control with technology in order to develop prosthetic neuromuscular control or sensory input of lost neurologic functions; and 2) the Communicative Disorders Program, which has developed a variety of treatments, techniques, and devices to aid the communicatively disabled to learn, maintain, or redevelop lost speech, language, and hearing capabilities.

The leading cause of blindness among Americans over the age of 50 is age-related macular degeneration. A nationwide clinical trial supported by the National Eye Institute has demonstrated that laser treatment can dramatically reduce the risk of visual loss from one form of macular degeneration. The NEI is also conducting a pilot study evaluating the usefulness of cyclosporine in treating uveitis, an eye disease responsible for 10 percent of all visual impairment in the United States.

NIH research activities are shared among other government agencies through various mechanisms. For instance, the Interagency Committee on Handicapped Research has established several subcommittees focusing on specific disabilities and coordinating related Federal activities. The NIH is represented on the membership of the Subcommittees on Visual Impairment, Hearing Impairment, Handicapped Children, Rehabilitation Technology, International Activities, and Mental Retardation and Developmental Disabilities.

Question: Has there been interaction and cooperation with the National Institute for Handicapped Research?

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Answer: The NIH maintains extensive ties with the National Institute for Handicapped Research through the Interagency Committee on Handicapped Research (ICHR), which is chaired by the Director, National Institute for Handicapped Research. The Interagency Committee is responsible for promoting coordination and cooperation among Federal agencies conducting rehabilitation research. The ICHR holds formal, quarterly meetings but functions more regularly through its subcommittees.

Recently, communication between agencies sharing an interest in rehabilitation research has been facilitated by an information system (known as IRRIS) encompassing data collection, thesaurus development, coding, data entry, storage, and retrieval from 50 data bases. NIH participated in this effort by contributing descriptors from its CRISP system and allowing access to this data bank. IRRIS serves the Interagency Committee as one means of promoting coordination through its production of an annual compilation of ongoing Federal rehabilitation research data by agency, specific subject areas, expenditures, etc. This compilation will allow an assessment of all rehabilitation research and identify gaps, possible duplications, and opportunities for collaboration. More importantly for NIH is the fact that it will provide the means for sharing our research findings with over 30 other Federal agencies involved in rehabilitation research.

Question: What can Congress do to foster a closer and more productive relationship between NIH and NIHR?

Answer: As indicated previously, the National Institutes of Health and the National Institute for Handicapped Research maintain a close, mutually beneficial relationship. The administrative link between the NIHR and the Interagency Committee for Handicapped Research (ICHR), as well as NIH representation on several ICHR subcommittees, provides a vital channel for communication and coordination of effort. The recent inception of the computerized information network, IRRIS, will further enhance existing ties between government agencies involved in the conduct and support of rehabilitation research.

Question: What efforts is the NIH making to disseminate NIH-supported research to local providers; e.g., hospitals and rehabilitation centers?

Answer: Over 80 percent of the NIH budget is devoted to funding extramural research conducted in academic institutions, teaching hospitals, and research centers. One type of research project that is particularly effective for disseminating information concerning advances in treatment and rehabilitation is the multi-center clinical trial. Designed and coordinated by NIH staff, the research protocol frequently instructs clinical investigators in the latest techniques in reconstruction surgery, post-operative prosthetic fitting, or amelioration of disabilities following treatment.

The Division of Research Resources funds 75 General Clinical Research Centers located primarily in teaching hospitals. Projects under way in these centers include studies on the loss of function, ways to rehabilitate individuals suffering from these disabilities, and the use of new techniques to improve the handicapped individuals' quality of life. Some Centers evaluate devices and prostheses such

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as small vessels, artificial limbs, eye muscles, and speech and hearing aids. Examples of recent technological developments which benefit the disabled are: voice controlled wheelchairs, talking typewriters for the blind, and computer output terminals in Braille.

NIH also disseminates research results through seminars and publication in scientific journals. Another mechanism is the consensus development conferences sponsored by the Office of Medical Applications of Research. One such conference gathered medical experts to examine and evaluate research findings on limb-sparing techniques used in the management of soft tissue sarcomas.

Through its participation in the IRRIS information system described earlier, NIH contributes information describing its rehabilitation research programs that will be accessible to interested Federal agencies as well as non-government groups including providers such as hospitals and research centers funded by the National Institute of Handicapped Research. As long as the National Institute for Handicapped Research and the Interagency Committee on Handicapped Research continue their important efforts to link over 33 Federal agencies involved in rehabilitation research, NIH will provide research results and technical expertise to remain an active partner in this enterprise.

INTRAMURAL RESEARCH PRIORITIES

Question: How are research priorities set for the intramural research programs at the individual Institutes?

Answer: Research priorities for intramural research programs in the different Institutes are set through a rather complex arrangement of review by outside groups, called Scientific Counselors, and review among the various Scientific Directors, the laboratory chiefs, and senior scientists of each Institute.

The review process is of course concerned with the potential productivity and quality of the proposed science; our primary interest lies in conducting research leading to the greatest possible benefit in improving treatment methods, developing cures, and preventing disease. The relevance of the proposed projects to the Institutes' missions is an additional consideration.

Question: Is there a formal review process set up to decide what research will be funded through the intramural program?

Answer: As indicated above, we have a very formal external review process to aid us in making such determinations. Each Institute has a Board of Scientific Counselors; the National Cancer Institute, because of its size, has three such Boards.

The Boards are composed of distinguished scientists, not connected with the NIH, who visit here for 2 or 3 days twice a year to conduct comprehensive reviews with all the scientists in any one or two laboratories on each visit. They prepare formal reports of their findings, and their evaluations play a major role in deciding which scientists will receive tenure, which will be promoted, and how many resources should be devoted to a given scientific group; in essence, which research projects will be funded through the Intramural Program.

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In addition to this formal, written, outside review process conducted by Scientific Counselors, there is a continuing review process within each Institute and among the Institutes through bi-monthly meetings of all the Scientific Directors of the various Institutes.

LAB RENOVATION ON THE NIH CAMPUS

Question: Last year Congress had to add back the funding to keep the laboratory renovation project on schedule. How much will be needed in 1986 to keep to building schedule?

Answer: We expect the laboratory renovation project to remain on schedule with the requested funds.

Question: How much have you requested in 1986 for this purpose?

Answer: We have requested $2.5 million for laboratory renovations in 1986.

REPROGRAMMING

Question: The Department is proposing new language (Section 212) for the 1986 appropriations bill that would give you the authority to reprogram 0.5 percent of the NIH budget. Please explain the reasoning behind this new authority.

Answer: The recently completed Institute of Medicine study of the NIH organizational structure cited the need for greater flexibility to fund special research needs and to meet public health emergencies. The study recommended that a discretionary fund be established and that limited authority be provided the Director, NIH, to transfer funds across Institute lines for this purpose. The Administration has proposed the 0.5-percent transfer authority as a way of enabling flexibility to devote resources to special problems.

Question: If you add more money to an Institute's budget for the purpose of funding new research, who will pick up the funding in the out-years for that project?

Answer: Any future year continuation costs would have to be provided by the Institute that made the original award. This would be taken into consideration in the development of the future year(s) budgets. The proposed language (Section 212) does require that research grants or contracts funded under this provision by any Institute be awarded only after consideration by the advisory awarding body of the full cost of such a grant or contract.

Question: Aren't you in effect increasing that Institute's budget for the next fiscal year?

Answer: The Institute or Division receiving the transfer would have increased commitments in the next year(s). This could have the effect of increasing the next year's funding or of reducing the amount of other new research that could be supported by that Institute later on. Such transfers would be but one factor among many that go into the development of an Institute's funding level for a subsequent year. Throughout the annual budget cycle NIH reevaluates competing priorities and emerging research opportunities

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and makes budget allocations based on a number of considerations within total resource levels that are provided.

Question: Would you be decreasing another Institute's budget base by this transfer, and in effect proposing a decrease in the following fiscal year?

Answer: It is true that another Institute's budget would be decreased for the year in which the transfer was made. It should be emphasized that this authority would only be exercised in the event of an unanticipated pressing need and after careful consideration of all our competing research priorities. As mentioned, such a transfer would be but one factor among many that go into the development of subsequent year funding levels.

Question: Would it be more appropriate to just budget a certain amount each year for your discretion?

Answer: If an annual discretionary fund were established for the Director, it would preclude the need for a transfer authority of 0.5 percent of the NIH budget, and special problems could be addressed without disrupting other research activities already in place. Such a fund would provide optimum flexibility for responding to public health emergencies such as AIDS and the "seeding" of suddenly emerging research opportunities that cut accross Institute diciplines.

NIH CENTENNIAL

Question: Dr. Wyngaarden, in 1987 the NIH will be 100 years old, marking a long, proud history of achievement in medical science. Have you begun planning for the centennial celebration?

Answer: We have begun to plan for centennial celebrations that will be held in Bethesda and Washington in late 1986 and 1987. Our plans also include collaborative observances at important research institutions and at the meetings of major scientific societies during the centennial year.

The Centennial Steering Committee has authorized the creation of a Centennial Advisory Committee of prominent scientists, physicians, and national leaders headed by former NIH Director Donald S. Fredrickson, who also serves on the Steering Committee. A centennial logo and motto have been adopted ("A Century of Science for Health"), and discussions are under way with the Smithsonian Institution and the National Academy of Sciences regarding centennial-related activities. The European Medical Research Council has just decided, at our request, to hold its 1987 meeting in Washington in recognition of the NIH centennial. Contacts have also been made regarding the centennial with INSERM (Institute Nationale de la Santé et de la Recherche Médicale), the French equivalent of the NIH.

Question: What resources will be necessary for this centennial?

Answer: We expect that funding for a number or the centennial events will be provided from private sources or host institutions. NIH funds will be required, however, for modest staffing, travel of official representatives, and preparation of historical exhibits, fact sheets, brochures, and other informational materials.

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Question: What plans have you made to date to get your message to the public and professional groups?

Answer: We have been in touch with several of the largest scientific organizations, reminding them that NIH will observe its 100th birthday in 1987. Each organization contacted had indicated that recognition will be given to the NIH centennial in its publications and programs. We will endeavor to make similar arrangements with all the major scientific and professional groups involved in health-related research and services.

The NIH normally sponsors a large number of scientific and professional meetings throughout the year, and reminders will be given to attendants at such meetings.

Two leading medical journals, The Journal of the American Medical Association and Medical World News have taken notice of the centennial and have already devoted extensive coverage to the history and accomplishments of the NIH in that context.

Our plans for informing the general public are still in development. We have, however, made a proposal for issuance of a commemorative postage stamp and are in conversation with television producers regarding programs and announcements on public television.

SMALL BUSINESS PROGRAM

Question: The Small Business Development Act requires NIH to support innovative research and development by small businesses. Do you have any anecdotal examples of successful projects completed by these grantees?

Answer: The NIH awarded its first group of SBIR Phase II grants in September of 1984. Therefore, it is premature to cite any examples of successfully completed projects. However, we can share with you information about one of our Phase II grantees who is considering marketing the prototype product that his company developed in Phase I while continuing further research in Phase II to improve and refine the product.

The advent of simple, rapid methods for analyzing DNA sequences has led to a major requirement for the day-to-day use of computers in the typical molecular biology laboratory. The low cost of microcomputers has generated interest in these machines as the most cost effective means of meeting this requirement. But the average molecular biology lab wishing to set up a microcomputer must choose the appropriate hardware from a variety of options as well as software written by other researchers that may be difficult to use and/or adapt to the selected hardware. Therefore, a great deal of time might be devoted to setting up and running a system.

DNAStar was awarded a Phase I grant to demonstrate the feasibility of developing a software package which could be run on the widely available IMB PC. It succeeded in doing so. The big problem that was identified was the low capacity of the hard and floppy disks of the IBM. The proposed solution was to include a tape cartridge in the system. A Phase II grant was subsequently made to develop the software package to run on different computers and to expand its capabilities to take advantage of lower-priced,

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more powerful microcomputers that will be routinely available in the near future.

Among other uses, this software will also allow researchers to access and manipulate effectively and more easily information stored in GenBank, a data base of nucleic acid sequences maintained by NIH under contract.

DNAStar is now ready to market the product developed during Phase I. It appears that this product will be superior to and less costly than other available packages.

Question: In your opinion, how is this program working?

Answer: We believe the program is working well. All 13 awarding components of the NIH are participating in the SBIR Program, which provides research funding to small businesses in the form of both grants and contracts (contracts were added in 1985). The National Institute of Neurological and Communicative Disorders and Stroke and the National Institute of General Medical Sciences are two components that have had especially successful experiences with the program. The average priority scores of funded Phase I and Phase II applications of these two Institutes in the last two rounds have been comparable to those funded in their regular grants program.

Question: Can anything be done to improve the program?

Answer: While the implementation of the SBIR Program has progressed well at NIH, there are some fundamental structural problems inherent in the program that, if resolved, could improve the SBIR initiative even further.

The first deals with the requirement that applicants/offerors must receive a Phase I award in order to eligible for Phase II. While we appreciate the intent of this structured process, we believe that the interests of both the small business community and the Federal agencies would be served by allowing occasional exceptions. These are instances where small businesses have completed their feasibility studies without SBIR funds and are ready to apply directly for Phase II support. In the area of commercialization where the lag time between product development and marketing is already unacceptably long to many, any strategy that will shorten the timeframe merits some consideration.

The second area of concern that we have centers on the haitus in funding between Phase I and Phase II and the 6-month duration of the Phase I period. The discontinuity in funding is distressful to most small businesses and particularly to those firms in biomedical research because they cannot simply halt their SBIR research projects at the end of the Phase I period and reactivate them 6-10 months later (if funded for Phase II). The appropriate disposition of personnel and resources as well as the need to maintain certain biological experiments in the interim between Phase I and Phase II become a very real hardship for these small companies.

Furthermore, based on our experience, approximately 25 to 30 percent of all Phase I awardees are unable to complete their projects within 6 months. Consequently, they must request time extensions to complete their Phase I activities.

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One possible means of addressing both of these problems simultaneously is to provide for a more flexible Phase I project period that could be up to 12 months long. In the ninth month, the small business may submit an application for Phase II funding. Allowing 6 months for the Federal agency to process, review, and make an award, the hiatus between Phases I and II could be reduced to no more than 90 days. This strategy would provide those firms that need more time to complete Phase I activities with the additional time and would also reduce significantly the funding discontinuity that is currently part of the SBIR Program.

INSTITUTE OF MEDICINE (IOM) REPORT

Question: The IOM study committee that was convened to review the organizational structure of NIH made a number of recommendations concerning the role and authority of the NIH Director. (See pages 5-6; 18-19; 31-35.) Is the NIH planning a formal response to the IOM committee's report?

Answer: The IOM organizational study report received a broad review within the NIH. The review was coordinated by the NIH liaison committee that was established to oversee the study. On the basis of this review, we met in February with the Chairman and several members of the IOM Steering Committee and the study staff to discuss the report.

Question: Specifically, what is your reaction to the recommendation that you be given greater budgetary authority, including a 1.0 percent discretionary fund to seed selected areas of research in the existing Institutes, as well as a limited authority to transfer up to 0.5 percent of the NIH budget across Institute lines in the case of a public health emergency? (Page 5, 32)

Answer: The NIH finds merit in the report's suggestion that some discretionary fund should be available to the Director. A 1.0 percent discretionary fund should provide sufficient resources to address both emerging cross-cutting research opportunities and the need to meet public health emergencies.

Question: How would you envision this to work?

Answer: A discretionary fund could be appropriated as "no-year" money for maximum flexibility as to the timing of its use. To the the extent the fund is used for special cross-cutting research initiatives or public health emergencies, it could be replenished as needed so that a certain balance would be available. The fund would be operated on a reimbursement basis with the particular Institutes that are identified by the Director, NIH, as meriting supplementary resources for these one-time needs.

Under the transfer authority the Director, NIH, would have the power to move appropriated resources between Institutes up to the 0.5-percent limit.

Question: In the absence of such authority, how have you handled public health energencies in the past, such as in the case of the Acquired Immunodeficiency Syndrome (AIDS)?

Answer: Generally, I believe that structural constraints

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have not seriously impeded the ability of the NIH to respond to special research opportunities or public health emergencies. As the history of AIDS funding shows, however, much could have been saved in terms of administrative and program efficiency if it had not been necessary to go through the supplemental appropriation process.

Question: The IOM committee recommended strengthening the Director's Advisory Committee by converting it to a more independent NIH Policy and Planning Council "to provide for the Director a continuous evaluation of the research mission and function of the NIH, and to advise the Director in the formulation of long-term plans and in setting research priorities" (p. 5, 32-33). What is your reaction to proposing greater independence for the committee that is designed to assist you as the Director of NIH in fulfilling your mission?

Answer: The NIH views the creation of an autonomous body of advisors, with its own staff and budget, with freedom to define its own agenda, and without the responsibility and accountability characteristics that accompany Federal employment, as unsound public administration.

When one looks at the history of the Advisory Committee to the Director, NIH (DAC), its evolution and changing role over time, and the extent to which it supports the Agency in the policy development process (none of which was addressed in the report), it becomes clear that the Committee has developed in ways that have strengthened the NIH Director's ability to manage the Agency, to deal with cross-cutting areas of concern, and to engage in broad policy development activities. To alter the role of the DAC to an independent body at a time when it is evolving into an effective unit would not only be counterproductive but also likely to weaken, rather than strengthen, the NIH Director's ability to manage the Agency.

Question: Do you agree with the IOM's belief that such independence will help make the committee more effective in fulfilling its responsibilities?

Answer: We do not agree with the view that an independent advisory committee to the Director, NIH, will be more effective in carrying out its responsibilities. At the time of the establishment of the DAC, the NIH held that experience with the use of an inter-council group of this nature in the discharge of the Director's function would provide useful insight into the need for further evolution of this or some other advisory arrangement. With changes recently made by the current NIH Director in the operation of the DAC, it is our firm belief that the DAC has evolved into an effectively functioning body and that its role in supporting the NIH is not, at this time, in need of significant alteration. The NIH will continue, as it has in the past, to examine the role of the DAC and make improvements designed to enhance its effectiveness.

Question: Regarding the creation of new Institutes at the NIH, the Institute of Medicine committee recommended a presumption against creating new Institutes unless a set of criteria were met. Do you feel there is a need for the creation of any new Institutes at the NIH at this time?

Answer: The IOM report states that NIH has reached a point at

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which there should be a presumption--to be overrridden only in exceptional circumstances--against additions at the Institute level, whether they are proposed to occur by fission or by transfer from outside NIH. Although a particular research area may benefit from the establishment of a new Institute, the overall manageability of NIH suffers from the cumulative effect of such additions. This is because new Institutes 1) fragment the scientific effort and diminish effective communication with key scientists in other Institutes; 2) add to the burden and difficulty of effective program coordination by the NIH Director and his staff; and 3) add to administrative costs without ensuring increased appropriations.

We fully endorse this view and do not believe there is a need at this time for the creation of any new Institutes at the NIH.

Question: Are there any major organizational changes that have been discussed with your Advisory Committee?

Answer: Based upon a review of past agendas and minutes, it is clear that major organizational changes have consistently been discussed with the Advisory Committee to the Director, NIH. These discussions have covered a wide range of organizational concerns, from the transfer of major organizational units into the NIH, legislative proposals directing change, NIH-initiated change, as well as significant program changes which establish new organizational relationships with other Agencies.

PROPOSED HEALTH SCIENCES BOARD

Question: The IOM Committee recommended the establishment within the DHHS of a Health Sciences Board "to oversee the health research organization, missions, priorities, and institutional management of the several elements of the Public Health Service..." including NIH. Do you feel such a Board would be effective?

Answer: The NIH is opposed to creating additional bureaucratic layering and establishing yet more administrative superstructures to be imposed upon current practices before determining that such current practices cannot deal with or could not be strengthened to deal with contemporary issues. This proposal would impose a significant set of additional relationships at the interface between biomedical research and congressional oversight, would further compound complex issues, and would contribute to the management burden of the PHS and all agencies. Specific concerns are as follows:

- o The proposal implies that the Assistant Secretary for Health and the PHS agency heads, acting collectively, are not adequately addressing cross-cutting concerns and organizational issues that fall at the boundary of the respective agencies. Not only is there no evidence to suggest that this is the case, but also no indication that any serious analysis of the issue was conducted.

- o This proposal does not fully recognize the direct and continuing role played by Congress in the oversight of the PHS.

- o It is doubtful that such a Board could conceivably perform the functions suggested for a single, complex agency, yet

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alone the entire PHS. Increasing membership on the Board would not address the concern.

- Such a Board would be costly and create yet another administrative, bureaucratic function at a time when administrative costs are being limited by Congress and reduced by the Executive Branch.

- No continuing advisory body in PHS has its own staff, budget authority, and resources to establish groups and panels and to commission studies. Such a body may not remain advisory; it could easily become another operating body in the management structure and in conflict with the responsibilities and authorities of the Assistant Secretary for Health and agency heads.

- Implementation of this recommendation would require additional administrative positions at a time when full-time equivalent position ceilings are being reduced.

- The comparison of this Board to a board of regents of a university does not fully recognize the differences between a university and a Government agency.

NIH PRIVACY OFFICE

Question: NIH's privacy office has come under recent criticism by this legislative body because of the agency's announcement that it would keep computerized records on members of Congress. Can you give us your views on the propriety of this practice, as well as on the utility of such a system?

Answer: For many years the Division of Legislative Analysis of the NIH Office of Planning and Evaluation has maintained manual files of publicly available information on members of Congress to assist NIH officials in preparing their testimony to be used before Congressional Committees, as well as in responding to the numerous requests received from members of Congress. The only information maintained was in the public domain. Since publication of the Federal Register notice of December 21, 1984, we have continued to examine this issue. In light of the comments that we have received, the NIH no longer maintains a system of congressional biographies.

RESEARCH PRIORITIES

Question: There has been continued discussion concerning the relative commitment of the NIH as a whole toward the following: basic research, disease prevention research, and disease-specific applied research. What percentage of the NIH research budget is used for each of these areas?

Answer: The NIH normally classifies its research and development activities into three areas: basic research, applied research, and development research, or B/A/D. For both 1985 and 1986, we estimate that the following percentages will apply:

Basic research.....	63%
Applied research.....	29
Development research.....	8
	100

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Research in prevention occurs in all these categories, as well as in the research training programs, which are not reflected in the B/A/D breakdown. Prevention research is estimated at 24 percent of the total NIH budget in 1985 and 1986.

RECOMBINANT DNA

Question: What is your opinion of the recent Office of Science and Technology Policy Federal Register notice on December 31, 1984, which discussed a proposed mechanism for the regulation of recombinant DNA products?

Answer: I believe that the recent OSTP Federal Register notice, entitled "Proposal for a Coordinated Framework for Regulation of Biotechnology," provides a promising and valid approach. The proposal was generated by the Cabinet Council Working Group on Biotechnology on which the NIH was an active participant.

Question: How will the Office of Recombinant DNA activities and the Recombinant DNA Advisory Committee adjust to this new proposal if it is accepted?

Answer: In my opinion, the NIH Office of Recombinant DNA Activities and the NIH Recombinant DNA Advisory Committee will adjust well to this new proposal if it is accepted. As stated on page 50904 of the Federal Register notice, "The National Institutes of Health Recombinant DNA Advisory Committee (RAC), established in 1974, has performed well in providing scientific assessment of recombinant DNA research proposals submitted from institutions that receive Federal funding and has reviewed on a voluntary basis experimental protocols submitted by industry. The current scientific review apparatus is, however, not designed to respond to all the scientific issues surrounding commercialization of biotechnology including the health and broad environmental effects of new commercial processes and products. Hence, the Working Group believes an expanded, coordinated scientific advisory structure is necessary to meet the increased and varied demands for scientific evaluation created by the needs of modern biotechnology."

Question: In your opinion, are there going to be enough interested, willing and competent scientists to serve on each of the five agency advisory committees, as is suggested in the proposal?

Answer: The number of scientists with expertise in disciplines related to biotechnology has grown significantly in recent years. Therefore, there should be no difficulty in recruiting capable committee members.

Question: What impact will such changes have on the implications resulting from the lawsuit against NIH and HHS brought about by Jeremy Rifkin and the Foundation on Economic Trends?

Answer: The proposed changes in the scientific advisory committee structure are not expected to have any impact on implications resulting from the Jeremy Rifkin lawsuit (Foundation on Economic Trends et al., v. Margaret M. Heckler et al., Civil Action No. 83-2714 in the United States District Court for the District of Columbia). The lawsuit centers on whether the NIH adequately complied with the National Environmental Policy Act (NEPA), which

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requires the preparation of Environmental Assessments for certain Federal actions. Independent of whatever changes occur in the scientific advisory committee structure, it will remain the responsibility of all Federal agencies to comply with NEPA.

ENDOCRINE SYSTEM

Question: Research relating to the endocrine system has a long and fruitful history. I understand that it is receiving more attention. How much has the NIH spent on research relating to this area in each of the past 5 years, and what is contemplated for 1986 and 1987?

Answer: Funding related to endocrinology research for the years 1981 through 1986 is shown below; estimates for 1987 are not available.

1981.....	$389,908,000
1982.....	426,736,000
1983.....	469,723,000
1984.....	547,159,000
1985 est.....	609,129,000
1986 est.....	576,818,000

Question: Should the NIH be placing more emphasis on this area, and if so, what amount of additional funding should be made available?

Answer: I belive that the amounts being expended in endocrinology research are sufficient to maintain the viability of this effort.

INSTRUMENTATION

Question: The Committee has been told that there may be a serious problem in the area of research instrumentation. Please provide the Committee with an analysis of this problem by category.

Answer: In a survey conducted by Westat, Inc., heads of departments in the areas of biological and medical sciences were asked to list up to three pieces of research equipment costing between $10,000 and $1 million that were most urgently needed. Forty-eight percent of the items listed were items costing between $10,000 and $40,000; 28 percent were items costing between $41,000 and $100,000; and 23 percent were items costing $101,000 to $1 million. The top three categories of instruments requested were preparative instruments, DNA analyzers-synthesizers, and electron microscopes.

Question: To what extent has the NIH shared instrument program helped? Should the limits on costs of instruments eligible for funding under this program be changed? Are additional funds for this program desirable?

Answer: The shared instrumentation programs at NIH have been very beneficial to the biomedical research community in alleviating the problems of acquiring expensive instrumentation. The instrumentation problem has many causes, not the least of which is the pace of technological progress, which may quickly render scientific instrumentation obsolete. Conversely, newly developed instrument

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capabilities often create new research opportunities. Instrumentation will remain a continuing problem in the foreseeable future. With the increased use of microprocessors, the development of new technologies, and the demand to update equipment, institutions will continue to be faced with the need to improve instrumentation, especially that shared by a broad group of users.

The NIH Instrumentation Review Committee is reviewing the adequacy of current instrumentation mechanisms. Simultaneously, advisors to the Division of Research Resources are reviewing the limits on the costs of instruments eligible for funding under the Shared Instrumentation Grant Program. The two committees will work in close coordination in assessing the concerns raised by the research community about the availability of funding support for instruments costing in the range of $10,000 to $100,000. Careful consideration of the instrumentation needs identified through the Westat survey and through program experience will be used to determine whether changes are needed.

With the regard to funding, effective technological support requires stable research support not only to maintain and sustain the current equipment inventory but also to ensure that new modalities that are continually evolving or being improved are accessible to keep research investigators on the frontiers of science. The amount requested in the President's budget for instrumentation is sufficient to keep the program on a reasonable track.

Question: What needs exist beyond those that can be met under existing programs? What suggestions do you have for meeting these needs?

Answer: Upon receipt of the Westat report, I appointed an Instrumentation Review Committee. The Committee is analyzing the report and reviewing current NIH programs as to their adequacy to meet the needs highlighted by the report. The Committee will make recommendations to me regarding any needed changes in policy or program structure.

Question: To what extent can these needs be met through indirect cost reimbursement? What are the advantages and disadvantages of using that approach for some types of instrumentation acquisition?

Answer: It was not until OMB Circular A-21 was amended in August 1982 that Federal agencies had the discretion to approve interest on equipment financing as an allowable indirect cost. This discretion was restricted to interest on externally borrowed funds. (Interest on a university's own funds used to finance equipment is not an allowable cost.) The university, therefore, must make the decision to borrow funds. This is generally considered imprudent and fiscally irresponsible by Boards of Trustees because there is no guarantee that indrect cost reimbursements will continue to be met in full. Furthermore, the loan principle must be repaid with university funds that are then diverted from educational activities to underwrite research.

Therefore, although the concept of indirect cost reimbursement of interest payments on funds borrowed to purchase research instru-

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mentation appears to be an attractive way of protecting direct cost repayment, it is not always practical nor in the best interest of one research institution. Perhaps the most cogent argument against the borrowing of funds and using the indirect cost as the vehicle to pay the interest is that the proposal runs counter to the intense effort being made by both the Federal Government and the institutions to keep the indirect costs down.

MULTI-INSTITUTE INITIATIVES

Question: In the past 10 years, the NIH has been developing initiatives which a number of Institutes have participated in. A major multi-Institute initiative regarding diabetes was established and has produced a jointly funded diabetes complications clinical trial. Other multi-Institute initiatives have included immunology, endocrinology, and nutrition. What is your view of the utility of multi-Institute activity and, if useful, what multi-Institute initiatives would be in place for 1986? How would such initiatives be operated to assure their utility?

Answer: The NIH has actively sought to identify areas of research that might profit from organized efforts to promote the mutual interests of the various NIH organizational components through the development of shared activities. Many important diseases, disciplines, and problem areas, because of their pervasive nature and broad implications, extend beyond the program interests of any single NIH Institute and engender special needs for the development of mechanisms to assure the orderly development of those fields.

For example, in recent years mechanisms have been established to facilitate multi-Institute activities in diabetes, arthritis, digestive diseases, cystic fibrosis, immunology, nutrition, endocrinology, disease prevention, epidemiology, clinical trials, research manpower development, Reye syndrome, "orphan" diseases, behavior and health, maternal and child health, toxicology, chronic renal disease, research resources, animal welfare, acquired immune deficiency syndrome (AIDS), and Alzheimer disease.

Most of these areas will undoubtedly continue to be the focus of multi-Institute activities in 1986. At this point I do not anticipate the development of any new initiatives, although as new needs and opportunities emerge it is conceivable that additional mechanisms will be created in response.

I believe these trans-NIH activities serve well to address cross-cutting areas of interest. For instance, where coordinating committees have been established, they have functioned to: 1) provide a forum for the exchange of information and the discussion of ideas and views; 2) strengthen and improve the NIH information systems for reporting on research and related activities in these areas of special interest; 3) facilitate discussion of specific areas of mutual interest and need; 4) identify areas of potentially wasteful duplication of effort; and 5) provide a focus and central point of contact for the NIH in dealings with other Federal agencies and outside organizations.

Where a sufficient commonality of interest exists among the Institutes, the function of the committees may extend beyond the role of information exchange and coordination and, in fact, involve the

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active promotion of collaborative activities through the sponsorship and facilitation of shared endeavors involving the joint development of goals, plans, and programs. In such instances the committees serve to: 1) promote the development of joint program announcements and requests for applications to alert the scientific community to specific goals, research needs, special funding plans, and opportunities in specific areas of research; and 2) facilitate the joint sponsorship of workshops, conferences, and symposia designed to identify areas of research need and to stimulate research in areas of highest priority.

These examples of multi-Institute cooperation to facilitate the efficient and effective conduct of biomedical research serve merely to convey the range of possibilities that exist. New mechanisms for achieving effective collaboration will continue to be developed and tested as experience is gained through participation in such collaborative activities.

PHYSICAL FACILITIES

Question: Regarding deteriorating physical facilities at our universities: If physical facilities are inadequate, to what extent can the problem be resolved under existing authorities for remodeling and renovation?

Answer: Research project grants supported by the Public Health Service currently have a limit of $100,000 or 25 percent of direct costs, whichever is less, on the amount that may be used for alterations and renovations in either laboratories or animal facilities. This limit is imposed administratively by the Department and PHS; however, NIH is empowered to make exceptions to the limit on a case-by-case basis.

The limit has not been raised since June 1, 1980, when it was changed from $75,000 to $100,000. (In 1963, the limit was $50,000; in 1972 the ceiling was raised to $75,000.)

The use of existing authorities for alterations and renovations ensures that the need for modifications is presented for evaluation in the context of the research project(s) that the modifications are intended to benefit, and it permits a relatively prompt infusion of dollars.

However, funds allocated in this manner are not as likely to provide the substantial amounts that may be needed, especially when the need for alterations and renovations spans the scope of many research projects. Furthermore, this authority is limited to alterations and renovations and does not permit construction. Construction authority must be legislatively mandated; alterations and renovations are limited to "interior arrangements" such as new flooring, partitions, and plumbing.

Question: If new construction is imperative, what are the advantages and disadvantages of a program similar to that authorized in P.L. 84-835, the Health Research Facilities Act of 1956? Or, alternatively, should each National Institute have a program similar to those now operating in NCI, NHLBI, and NEI?

Answer: The Health Research Facilities Act (HRFA) authorized

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the Public Health Service to award matching grants for the construction, expansion, remodeling, or alteration of non-Federal, nonprofit facilities engaged in research in "the sciences related to health."

From 1957 to 1969, a total of $473 million was awarded under P.L. 84-835 in 1,482 grants to 407 institutions (in all States plus the District of Columbia). No funds were appropriated for the program after 1969, and the authority itself was repealed in 1976.

The enaction of some variant of the HRFA would have several advantages: It would result in long-term, comprehensive authority; a separate act would focus attention on and permit debate of the issue; and a separate act with its own appropriation would avoid conflict over the issue of whether public funds should cover construction costs, along with other costs of research (e.g., personnel, supplies, equipment).

In this time of fiscal constraint, however, such a proposal may appear to be too costly, and the creation of a national program along the lines of the HRFA might impede or delay the participation of non-Federal financial sources.

Question: Under the principles stated and the practices allowed in the current version of OMB Circular A-21, the construction of new facilities for research is possible. What are the relative advantages and disadvantages of this mechanism, as opposed to a dedicated construction appropriation, as in P.L. 84-835?

Answer: The provisions of OMB Circular A-21 permit the inclusion of the costs of interest payments on loans for capital expenditures in the calculation of the indirect costs of grants and contracts.

This method is particularly advantageous to grant and contract recipient institutions that have large Federally funded research programs, access to substantial loan funds, and a large pool of investigators whose ability to attract Federal research support over time is well established. These institutions can pursue ambitious facilities development programs. Disadvantages of this approach include the fact that Federal research funding agencies are required to distribute increasingly larger proportions of their budgets through indirect costs over which they can exercise no control. Such an approach could place the research dollar under greater pressure. Also, agencies cannot guide the development of facilities in directions that would benefit their missions, yet are required to pay for construction through indirect cost expansion. Further, it is unlikely that increased indirect cost payments will account for more than a fraction of the needs of institutions for financial assistance in meeting their research facilities construction and renovation requirements. They may be of little or no benefit to institutions whose research programs, while excellent, are not large enough to generate very substantial indirect costs.

A dedicated construction program reverses these disadvantages. With this approach, the agencies can plan construction support programs that address the perceived needs of advancing research and can guarantee that construction funds will be made available to institutions whose plans are regarded as most meritorious by their peers.

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Question: Would the indirect cost method or the dedicated appropriation relate the construction of new research space more or less closely to research priorities, as reflected in project and center grant awards?

Answer: Dedicated appropriation construction programs can be related directly to Congressional and agency research priorities. The indirect cost method gives individual institutions complete control over construction decisions which may bear no relation to Federal research priorities.

Questions Submitted by Senator Mark Andrews

BUDGET REQUEST

Question: For 1986, the Administration's request for the NIH is $4,852,680,000. This is a decrease of $282,048,000 from the 1985 level. What was your budget request to the Administration?

Answer: The NIH request to the Public Health Service (PHS) was $6,117,641,000; the PHS request to the Department was $5,138,925,000, and the Department's request to OMB was $5,605,009,000. The 1985 base used for the development of the NIH request to PHS and the PHS request to the Department was the President's budget of $4,566,453,000. The base for the Department's request to OMB was the 1985 appropriation level of $5,149,985,000.

RESEARCH TRAINING

Question: Our government's investment in biomedical research over the last several decades has resulted in a healthier America. This kind of investment saves dollars in future years. The strides we have made in research appear to be jeopardized in the proposed NIH budget. Not only has this budget proposed to freeze the number of research trainees (9900) for next year, but their stipends are also frozen at 1985 levels. Are we in jeopardy of losing many of our young, gifted scientists to foreign countries, who may be willing to offer better stipends?

Answer: The stipend levels implemented with 1985 funds were devised to be competitive. Information from the scientific community assures us that the stipends are now adequate to retain young scientists through the early research training period. It is estimated that the current stipend levels will continue to attract the seriously interested, well-qualified scientist into research training and career development programs through 1986.

Questions Submitted by Senator William Proxmire

ALTERNATIVE GRANT STRATEGIES

Question: Dr. Wyngaarden, in early 1982 two biomedical researchers sent a letter to Science Magazine suggesting alternatives to the current NIH grant system that would make it possible for the NIH to make more grants. In view of the large number of unfunded

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awards that would result from the Administration's multiyear obligation strategy, I'd like to explore one of those suggestions with you.

The first suggestion was the development of a system that would allow top-priority scored applications to receive 100 percent of their study section approved budgets while others with lower but very respectable priority scores--say half of all approved applications--would be funded on a sliding scale, receiving only a portion of their approved budgets, depending on priority scores.

I understand the Veterans Administration uses such a system. Has the NIH considered this approach?

Answer: NIH has, indeed, devoted considerable attention to suggestions to adopt the "sliding scale" approach to funding grant applications, aiming to distribute funds over a larger number of investigators than normally could be the case. After many discussions among staff and with advisory groups, however, the NIH has concluded that several weaknesses in the proposed system outweigh the presumed advantages:

- o The proposal does not allow for either the program relevance recommendations by National Advisory Councils and Boards or the judgments of BID Directors and their staffs in making award decisions. The NIH would abdicate its statutory responsibility were it to allocate funds simply by attenuating the recommended budgets for grants in accordance with patterns based solely on technical merit ratings; i.e., priority scores.

- o The proposal seems to rest on the assumption that essentially every project is readily adjustable in scope and/or pace over a wide range of support, including significant budget cuts below those recommended by peer reviewers as reasonable to accomplish the projects. In practice, many awards surely would be a waste of money, or at least suffer unwarranted distortions in the projects, if they were made at dollar levels significantly below those recommended.

- o Without substantial means for institutions to make up deficiencies in funds for projects with signifcantly reduced budgets, as seems likely, investigators would have little chance to achieve the results anticipated in the first rounds of review and would therefore fall short of expectations and fail in attempts at competitive continuation applications.

UNSPENT NIH GRANT FUNDS

Question: Dr. Wyngaarden, over a year ago the General Accounting Office sent a letter to Secretary Heckler stating that NIH could realize a one-time funding windfall of between $41 million and $143 million by offsetting grantees' estimated year-end unspent grant fund balances against the next period's grant awards.

In view of the funding crunch created by the Administration's decision to reduce the level of new and competing awards after the first round of awards had been made, this one-time windfall might prove very useful. Have you considered adopting GAO's suggestion?

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Answer: The infusion of additional funds in 1985 for research project grants would have no impact on the number of awards that could be made this fiscal year. It is important to keep in mind that the Administration has not reduced funding, but rather has proposed that the number of grants be reduced by multiyear funding a portion of the 5,000 level. Therefore, if additional money were to become available, it would mean only that more grants would receive multiyear funding, but the overall level would remain at 5,000.

With regard to the GAO report, we believe that is was seriously misleading in alleging that the NIH is failing to take advantage of millions of dollars of unspent funds or unobligated balances in grantee accounts.

First of all, "unobligated balances" should not automatically be construed as a large amount of money sitting idly in a grantee account. Much of an unobligated balance frequently consists of funds available within the letter of credit payment system but not yet drawn down by the grantee. An unobligated balance is simply the difference between the amount authorized for expenditure by grantees and the amount actually expended. The unobligated balance in any given year is typically less than 2.5 percent of the amount authorized.

Almost invariably, unobligated balances arise as a result of substantive programmatic reasons - such as delays in recruiting the necessary number of patients or gaining access to critical instrumentation or the discovery of an unexpected lead that alters the course of the research. Because of this, it is imperative that NIH program managers have the option to either conserve the funds for their original purpose or use them as an offset to future year costs of the project.

The process by which NIH ultimately uses these funds is not an arbitrary one, devised by NIH irrespective of Federal guidelines. Instead, the current NIH practice is rooted in the official Federal, Departmental, and Public Health Service regulations and policies governing research grants.

Each year, NIH offsets its current year requirements for noncompeting continuation awards by approximately $60 million of prior year unobligated balances. This practice is also factored into the methodology by which NIH estimates its full funding requirements for the year of its appropriation request.

GAO also recomends that, when an unobligated balance is used as an offset, this should be done in the same year in which the unobligated balance is reported and not in the subsequent year as is the current NIH practice. However, to make such a change would be most inefficient and costly. Revision of grant awards immediately upon report of an unobligated balance (instead of waiting 6 to 7 months for the start of the next fiscal year) would necessitate the repetition of almost the entire grant awarding process in terms of internal reviews, document processing, and calculation of indirect costs. The additional administrative burden on NIH would be enormous. By waiting instead until the start of the next funding cycle, NIH is able to make far more efficient use of its limited resources.

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MEDICAL PRACTICES

Question: Dr. Wyngaarden, last fall this Subcommittee held a hearing on variations in medical practice patterns. The hearing focused in part on research into the long term outcome of certain commonly used surgical procedures. Can you tell us if NIH plans to support any work in this area next year through research grants, intramural research or consensus conferences?

Answer: NIH's current research in the evaluation of surgical procedures is more focused on relatively newly introduced operations, especially in the fields of cancer and cardiovascular surgery, than it is on the older procedures like hysterectomy, appendectomy, and prostatectomy. We plan to continue the current effort, through extramural mechanisms, well into the future so that long-range outcomes can be documented. Such studies are better done through grants and contracts with academic, general, and community hospitals than in the NIH Clinical Center, since the latter serves as a tertiary referral hospital, and does not have access to the common medical problems that are ordinarily handled closer to the patient's home.

The list of possible topics for consensus conferences during the coming year includes two that will undoubtedly have implications for the indications for common surgical procedures. These are management of prostatic carcinoma and treatment of kidney stones. It is too early to announce a date for either of these meetings, or indeed to be certain that early planning will be successful in leading to a full conference.

AIDS RESEARCH

Question: Dr. Wyngaarden, a recent report to the Congress on the AIDS issue by the Office of Technology Assessment (OTA) said that the AIDS crisis has raised the question of how research funding can be accelerated in public health emergencies without compromising the quality of research to be supported. Do you consider this to be a problem and is NIH exploring the question?

Answer: I do recognize this as a problem, but not as a simple one. I do not believe that research funding can be accelerated with no compromise of quality; the question is to what degree is compromise of quality acceptable? In the case of AIDS, one must also remember that the very existence of an emergency was not uniformly recognized at the outset; time had to pass, and more cases be reported before it was clear that the first clusters of cases were not a self-limited outbreak of no wide consequence. For these reasons, many of the best research minds and most fully equipped laboratories, which were already deeply committed to research on other important diseases, were not moved to abandon other fruitful research and tackle AIDS immediately. Thus, some of the earliest proposals for research on AIDS that were received by the NIH were of marginal quality. I believe that the NIH has learned, and is continuing to learn, through the experience of the AIDS emergency.

Question: A second question OTA raised as a result of its AIDS study was how access to commercially sponsored research might be improved without infringing on the property rights of commercial enterprises. Do you see this as a serious problem?

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Answer: There is a well defined body of legislation which covers this situation whereby government can and does work with commercial organizations to utilize some of their research findings without infringing on their rights. In those areas where a commercial product is a possibility, the commercial importance of the finding will dictate the emphasis placed on the research by the organization. The government can and does assist when the public good can be advanced. In some instances of high commercial importance no assistance is needed, and as the findings lead to a commercial product the research findings are made public. In areas where there is little or no commercial benefit to the organization, but the research findings are important (as with orphan drugs), the government can work with the commercial organization to develop the findings to the point of demonstrating efficacy and allow the commercial organization to retain rights for marketing. There are no problems visualized that would be an obstacle to collaborative efforts between commercial organizations and the government; the nature of the agreement and retention of property rights could be clearly stipulated at the outset.

INDIRECT COSTS

Question: Dr. Wyngaarden, on page seven of your prepared statement you indicate cost rates associated with research grants will be held at the 1985 rate, saving $23 million. I assume this does not mean that you will refuse to allow a grantee to adjust the indirect cost rate downwards, or does this never happen?

Answer: Yes, there are occasions when the indirect cost rate for an institution is lower than the previous year. The lower rate is used in such instances. If in 1986, the indirect cost rate is lower than 1985, the 1986 rate would be used.

Question: Last year Secretary Heckler mentioned a study of indirect cost policy by the President's science advisor. Can you tell us where that study now stands?

Answer: Staff of the DHHS are providing data and technical assistance for the Office of Science and Technology Policy (OSTP) inquiry. Specifically, because the DHHS negotiates the indirect cost rates for approximately 95 percent of the institutions of higher education that receive research funds from agencies of the U.S. Government, the Assistant Secretary for Management and Budget, DHHS, is in a unique position to display trends and describe the alternative approaches to defining indirect costs pools.

OSTP had earlier appraised DHHS that the report on the health of the research-intensive universities should be available early in calendar year 1985. The DHHS expects to receive the report soon.

Question: Dr. Wyngaarden, wouldn't it make sense to have a uniform indirect cost policy for the entire Federal government so that a university would apply the same ground rules to NIH and National Science Foundation grants, for example?

Answer: It would make eminently good sense to have a uniform indirect cost policy applicable to all research grants awarded by

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the Federal government, and we are hopeful that current efforts of the OSTP regarding their study of indirect costs will produce the impetus for such uniform policy. For example, while both the DHHS and the National Science Foundation use the Indirect Cost Negotiation Agreement as the guide for determining the original amount of indirect cost to be provided under a particular research grant, the DHHS allows additional amounts of indirect cost to be recovered based on the rates in effect during the entire length of the grant, whereas the National Science Foundation has no similar adjustment policy.

Question: Last year you estimated that indirect costs would consume 31.6 percent of each grant dollar in 1985. If indirect costs were not frozen next year, what percent of each grant dollar would they absorb?

Answer: If indirect costs are not frozen in 1986, it is estimated that 32.2 percent of each grant dollar will be used for these costs.

MULTI-INSTITUTE INITIATIVES

Question: Over the years NIH has developed a number of mult-Institute initiatives. A good example is the jointly funded diabetes complications clinical trial. Other initiatives have involved immunology, endocrinology, and nutrition. Can you tell us what multi-Institute initiatives you are currently conducting and indicate what projects you plan to start in 1986?

Answer: In recent years, mechanisms have been established to facilitate multi-Institute activities in diabetes, arthritis, digestive diseases, cystic fibrosis, immunology, nutrition, endocrinology, disease prevention, epidemiology, clinical trials, research manpower development, Reye syndrome, "orphan" diseases, behavior and health, maternal and child health, toxicology, chronic renal disease, research resources, animal welfare, acquired immune deficiency syndrome (AIDS), and Alzheimer disease.

Most of these areas will undoubtedly continue to be the focus of multi-Institute activities in 1986. At this point I do not anticipate the development of any new initiatives, although as new needs and opportunities emerge it is conceivable that additional mechanisms will be created in response.

Question: How do you determine the lead Institute for these multi-Institute initiatives? It seems to me that there might be some potential for conflicts between Institutes.

Answer: In many cases the designation of a lead Institute is clear, based on that Institute's major involvement in the relevant area. However, in customary practice the lead Institute designation is not a primary consideration since the participation of all affected organizations is assured. The NIH has actively sought to identify areas of research that might profit from organized efforts to promote the mutual interests of the various NIH organizational components through the development of shared activities. Many important diseases, disciplines, and problem areas, because of their pervasive nature and broad implications, extend beyond the program interests of any single NIH Institute and engender special needs for

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the development of mechanisms to assure the orderly development of those fields.

I believe these trans-NIH activities serve well to address cross-cutting areas of interest. For instance, where coordinating committees have been established, they have functioned to: 1) provide a forum for the exchange of information and the discussion of ideas and views; 2) strengthen and improve the NIH information systems for reporting on research and related activities in these areas of special interest; 3) facilitate discussion of specific areas of mutual interest and need; 4) identify areas of potentially wasteful duplication of effort; and 5) provide a focus and central point of contact for the NIH in dealings with other Federal agencies and outside organizations.

Where a sufficient commonality of interest exists among the Institutes, the function of the committees may extend beyond the role of information exchange and coordination and, in fact, involve the active promotion of collaborative activities through the sponsorship and facilitation of shared endeavors involving the joint development of goals, plans, and programs. In such instances the committees serve to: 1) promote the development of joint program announcements and requests for applications to alert the scientific community to specific goals, research needs, special funding plans, and opportunities in specific areas of research; and 2) facilitate the joint sponsorship of workshops, conferences, and symposia designed to identify areas of research need and to stimulate research in areas of highest priority.

These examples of multi-Institute cooperation to facilitate the efficient and effective conduct of biomedical research serve merely to convey the range of possibilities that exist. New mechanisms for achieving effective collaboration will continue to be developed and tested as experience is gained through participation in such collaborative activities.

Questions Submitted by Senator Quentin N. Burdick

FUTURE OF CLINICAL RESEARCH

Question: My first question concerns the future of clinical research. Do you see clinical research being curtailed in the future because of the new prospective reimbursement system under Medicare? Such prospective payment systems will probably become more common in the future. What plans does NIH have for ensuring that clinical research will continue in the new, more cost-conscious health care environment?

Answer: Implementation of Medicare's prospective payment system has important implications for every aspect of health care including the conduct of clinical research. Due to the perception that patients enrolled in clinical trials are more expensive to treat than others, these studies may be threatened by hospital administrators who view the DRG (diagnostic related group) limit as a disincentive to participation in clinical research programs.

In order to prevent the disruption of ongoing trials and to

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ensure the future of clinical research, responsibility for patient care costs must be examined and clarified. According to the Medicare Provider Reimbursement Manual, the costs of research may not be covered by Medicare. However, usual patient care costs are reimbursable even when provided in conjunction with the conduct of research. Extraordinary costs such as additional hospitalization or test procedures required for investigational purposes are the responsibility of the research institution.

Under cost-based reimbursement, this distinction was not clearly defined. Today's heightened cost-consciousness has engendered a more strict interpretation of research-related charges. The Health Care Financing Administration bears a responsibility to provide clear guidelines to the local carriers who make line coverage decisions, and other health insurance providers should be encouraged to follow this lead.

We have taken several steps, in conjunction with other agencies in the Department of Health and Human Services, to assess the impact of prospective payment on our clinical research programs. An NIH Planning Group on Prospective Payment has been established to collect information from hospital-based researchers as the system is phased in, and to communicate our experience and views with other agencies. This group is qualified to offer assistance to the Health Care Financing Administration in defining research vs. state-of-the-art patient care.

The National Cancer Institute and the National Center for Health Services Research are conducting a study to compare the costs of providing hospital care for cancer patients enrolled in clinical trials with those of similar non-research patients. Preliminary results indicate that patients on research protocols may not be more expensive to treat. Although this study may provide useful information regarding cancer patients, we feel that its results cannot be extrapolated to other Institutes. The study will not be completed until 1986.

Furthermore, the immediate impact of prospective payment on clinical research is more likely to result from the efforts of hospital administrators to cut costs. We support the intent of the architects of prospective payment to induce more efficient behavior in the nation's health care delivery system. However, NIH-supported clinical trials may be jeopardized if attempts are made to shift patient care costs to research grants. This can only be prevented if third party payors are instructed that patients who require hospitalization for treatment of their disease are eligible for insurance coverage, regardless of research status.

PROFESSIONAL LIABILITY

Question: What impact is the question of professional liability having on biomedical research? Is there any evidence that young investigators are shying away from more experimental types of medical research because of liability questions?

Answer: It is difficult to evaluate the effect of professional liability upon biomedical research. Investigators of all ages who are licensed to provide clinical care normally carry malpractice insurance. In some instances, they pay the premium themselves; in

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others the premiums are paid by the institutions for which they work.

There is anecdotal evidence in the medical research community that the regulations governing research involving human subjects have added another layer of complication and paperwork to an already complex system. While this has been a disincentive to the marginally interested, it does not appear to have had a serious effect on the conduct of research involving human subjects.

Questions Submitted by Senator Daniel K. Inouye

HEALTHY PEOPLE

Question: The committee is very interested in the NIH developing a research program which will explore the scientific recommendations contained in HEALTHY PEOPLE. Last year, the committee included an additional $7 million for these projects. What has NIH done in this area?

Answer: The NIH is actively encouraging research proposals related to health and behavior as recommended in the Surgeon General's report, "Healthy People." Because so much behavioral research is related to disease prevention and health promotion, the NIH staff coordinators responsible for administering these important initiatives have taken special steps to increase the opportunities for soliciting and funding research in these areas. During the past 3 years, the NIH has issued many Requests for Applications (RFAs) dealing with research on behavioral modification as it may impact on reduction of disease incidence. These requests have ranged from smoking and its effect on heart disease, cancer, and stroke to the role that diet, nutrition, and physical fitness play in preventing cancer, diabetes, osteoporosis, and many other diseases, including a slowing of the aging process itself.

Question: What are the the NIH's plan during this fiscal year to address these recommendations?

Answer: The NIH has undertaken, and will continue, a broad-based effort in disease prevention, particularly in the areas of behavioral and social science research. The following are examples:

- The NIH Coordinating Committee on Disease Prevention and Health Promotion was created to increase efforts and accountability for disease prevention and health promotion. The Committee, which includes representation by all the Institutes, will continue to meet on a monthly basis.

- Two senior staff personnel have been assigned within the Office of the Director, NIH, to devote the major portion of their time to coordination of disease prevention efforts.

- A Working Group on Health and Behavior has been established, which meets regularly and includes representation from most Institutes. The chairman of this working group serves as liaison member to the NIH Coordinating Committee for Disease Prevention.

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- o A meeting on "Research in Prevention" is planned for mid-1986. This important conference, which will be cosponsored with the Office of the Assistant Secretary for Health, is intended to provide a forum for increased scientific awareness of the state-of-the-art that will enable investigators to prepare and submit new and innovative approaches to furthering the science of disease prevention.

- o A seminar series on health and behavior issues has been initiated.

- o Communication of pertinent information and program ideas will be continued within NIH and with ADAMHA and other agencies interested in disease prevention.

- o The NIH will continue to issue Requests for Applications in a broad range of disease prevention areas, including many in the behavioral and social science areas.

Question: The committee expects to again include specific funds and a directive targeted towards the recommendations of HEALTHY PEOPLE in the 1986 bill. How can the committee ensure that NIH will follow congressional intent this time to target projects in this area?

Answer: The NIH will continue to work toward fulfilling the recommendations presented in the Surgeon General's report. A significant number of NIH scientific personnel were instrumental in developing the discourse and recommendations contained within this seminal document. In addition, appropriate NIH scientific and health promotional staff have met on a regular basis with the Assistant Secretary for Health to review and comment on the "Objectives for the Nation" as they apply to the 15 DHHS Prevention Initiatives.

Regarding expenditures of funds, the NIH plans to continue making disease prevention and health promotion a priority area, including health and behavior studies targeted toward modifying lifestyle that could help reduce disease morbidity and mortality. This effort will involve many interdisciplinary studies ranging from anatomy and biochemistry to psychology and the social sciences; specific amounts will not be targeted for these individual research areas.

The absence of a specific targeted initiative, however, has not prevented the implementation of research on the relationship of behavior and lifestyle to health. According to recent estimates, NIH's commitment to social and behavioral research has grown from approximately $104 million in FY 1983 (actual) to greater than $137 million in FY 1985 (estimated). This increase considerably exceeds the rate of growth of the NIH budget overall. The trend reflects not only a desire on the part of NIH to foster investigations of the behavioral factors that may underlie the major killer diseases, but also a growing concern on the part of the broader scientific community. There has been an impressive increase from 1980 to 1983 in the number of grant applications submitted to NIH that were related to social and behavioral science.

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MINORITIES

Question: Last year the Committee expressed its concern that insufficient numbers of minorities have been appointed to various advisory committees of the NIH and, further, that less than 1 percent of all NIH funding went to the 114 historically Black colleges and universities combined. The committee directed the NIH to establish a special task force similar to that which it has for the nurses. Was such a task force established; how many times did it meet; what recommendations has it made? The Committee would also like to learn the composition of the task force and, in particular, the number of native Americans (American Indians and native Hawaiians) who might have been appointed.

Answer: During the past year, the participation of women and minorities in NIH public advisory committees was studied in depth by the NIH Extramural Program Management Committee (EPMC), the senior staff group responsible for guiding the implementation of policies and procedures affecting grants, cooperative agreements, and contracts. Through its Subcommittee on Equal Opportunity for Access in Extramural Programs and associated ad hoc working groups, the EPMC continually promotes and oversees the evergrowing array of grants and related initiatives specifically oriented to women and minorities. In the particular case of public advisory committees, a special working group analyzed appointments with respect to gender, race, and ethnicity and made recommendations for achieving better balance of membership. The working group consisted of three Blacks and five Caucasians; five of the eight were women. The working group met 11 times, for approximately 4 hours each time.

The working group reviewed the appointments to public advisory committees for the period 1979-1984. The total membership of the committees increased from 1,950 in 1979 to 2,365 in 1984, a 21 percent increase. During this period, the number of minority advisors increased by 48 percent (249 in 1979 to 369 in 1984). In 1984 women and minorities accounted for 21 percent and 16 percent, respectively, of the total membership of the public advisory committees.

Although the aggregate statistics for women and minorities are encouraging, analysis of the data with respect to particular minority subgroups revealed a need for further and more focused recruitment. That is, the increase in the number of minority advisors was achieved mainly through the appointment of Asians (99 in 1979 to 172 in 1984). While there was an increase in the number of Blacks appointed to the public advisory committees from 1979 to 1981, there was a decrease by 1984 (99 in 1979; 128 in 1981; 98 in 1984). Other minority subgroups showed an increase, with Native American advisors increasing from 2 in 1979 to 11 in 1984 and Hispanic advisors increasing from 54 in 1979 to 87 in 1984.

The working group made the following recommendations:

- All NIH staff--but in particular executive secretaries, supervisors of executive secretaries, and program officials--must make a concerted effort to identify, nominate, and appoint more minority and women advisors.

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- o The NIH should amend its policies and procedures (e.g., those affecting geographical distribution and length of service) to allow exceptions which would facilitate the appointment of more minority and women advisors to public advisory committees.

- o The NIH must support the training of more women and minorities in the biomedical sciences.

- o The NIH Consultant File must be improved if it is to be an effective resource for identifying women and minority advisors.

The recommendations have been accepted by the Extramural Program Management Committee, and their implementation soon will be considered by the Directors of the NIH Bureaus, Institutes, and Divisions and by staff of the Office of the Director, NIH.

NURSES IN RESEARCH

Question: For the past several years, the Committee has been very interested in ensuring that the NIH will give greater prominence to nursing research activies. We understand, for example, that professional nurses represent less than one percent of the public advisory committee membership and, further, that only approximately $1.5 million of the 1983 budget was allocated to schools of nursing. The committee is aware of the Department' NIH Task Force on Nursing Research and commends the Director for establishing this group. The Committee would like to receive updated figures regarding both the proportion of nursing membership on advisory commitees, as well as information regarding how much of the 1984 budget went to schools of nursing.

Answer: The NIH encourages the use of nurses on its public advisory committees. Currently 12 nurses are serving: six on initial review groups and six on the NIH advisory councils and boards, including one ex-officio member. While this is a small proportion of the total membership of the NIH public advisory committees, it should be noted that nursing research is only tangential to the overall mission of the NIH; i.e., the support of basic biomedical research.

In 1984, 25 awards were made to 14 schools of nursing for a total of $1,648,000.

Question: The Committee also desires to learn of the NIH's plan for implementing the various recommendations of the NIH Task Force on Nursing Research, especially those recommendations which can be done administratively, such as adopting the two major systems, IMPACT and CRISP, to track nursing research activities at NIH and also establishing a post-doctoral resident fellow's program at NIH for senior and mid-level nurse scientists working in nursing research.

Answer: The Division of Research Grants is currently working with the IMPACT and CRISP systems to improve their capacity to track nursing research. The Division is expanding the degree information in the computer to include the RN degree as well as associated

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degrees. In some instances the nurses will include their highest degree (e.g., Ph.D.) and the RN is not in the IMPACT file. The terms used in the thesaurus of research topics is being expanded to include more topics relating to nursing research, rendering the CRISP system more efficient in this area. These measures will greatly assist the NIH in tracking nursing research activities.

A program to help train nurses in nursing research has been initiated. The program was advertised in the Journal of Nursing Research, Association of American Colleges of Nursing, and the Chronicle of Higher Education. The first trainees are to start training this summer.

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NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

STATEMENT OF DR. CLAUDE LENFANT, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. JAY MOSKOWITZ, ASSOCIATE DIRECTOR FOR SCIENTIFIC PROGRAM OPERATION, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

WILLIAM BELDON, CHIEF, PUBLIC HEALTH SERVICE BUDGET BRANCH

BUDGET REQUEST

Senator WEICKER. The committee will next hear from Dr. Claude Lenfant, Director of the National Heart, Lung and Blood Institute.

This Institute supports a multifaceted research and education program primarily directed against heart disease, the leading cause of death in the United States.

The 1986 budget request for this Institute is over $775 million, a decrease of over $28 million from 1985 current estimates.

Dr. Lenfant, it is a pleasure to have you with us. Proceed as you see fit.

Dr. LENFANT. Thank you; first I would like to introduce Dr. Moskowitz with me. Dr. Moskowitz is the Associate Director for Scientific Program Operation.

I am pleased to appear again before this committee and to have the opportunity to amplify some of my written testimony. I would like to give you some examples of progress and new studies that promise to translate into better health for the American people.

COOLEY'S ANEMIA

For example, research on thalassemia, or Cooley's anemia, has reached new peaks, following years of work during which molecule-by-molecule studies have led to an understanding of what goes wrong in this disease. Today, Cooley's anemia can be diagnosed before birth. It is now possible to switch on the production of normal hemoglobin. In the near future it may be possible to implant healthy blood forming tissue. Furthermore, the prospect of correcting genetic mistakes by normal gene transplantation is now a possibility.

CHRONIC OBSTRUCTIVE LUNG DISEASE

I am also glad to report that years of work to uncover the cellular and biochemical mechanisms of chronic obstructive lung disease are

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beginning to have an important clinical impact. It is now well established that lung tissue destruction is the consequence of an imbalance between enzymes. Today, there is a possibility that this enzyme imbalance may be corrected by using a protein extracted from human blood or, even better, from a protein produced by recombinant DNA techniques. The importance of this research must be viewed within the context that diseases of the lung continue to escalate and that chronic obstructive lung disease is the fastest rising cause of death in the United States.

CARDIOVASCULAR DISEASE

Finally, Mr. Chairman, I wish to emphasize some promising directions in the cardiovascular disease program. Laser technology is becoming an instrument that offers hope as a means to remove obstructions in blood vessels, especially in the coronary arteries. It also holds promise as a means to excise abnormal tissue in the heart without the lengthy and complex procedure of open heart surgery.

Last year, as you may recall, Mr. Chairman, I reported the results of a major study which demonstrated a decrease in the risk of heart disease when blood cholesterol levels are lowered. The Institute is now initiating a Cholesterol Education Program in consultation with various Government agencies, professional organizations, and representatives of the food industry. This public health education program will have considerable impact on efforts to reduce the incidence of heart attacks.

To conclude, Mr. Chairman, the Institute continues to make progress by fostering a balanced program that includes basic and clinical research, clinical trials and prevention and education activities that are supported almost entirely by individual research grants and center grants.

I will be pleased to answer questions.

PREPARED STATEMENT

Senator WEICKER. Thank you. Your statement will be inserted in the record at this point.

[The statement follows:]

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Statement of Dr. Claude Lenfant

I am pleased to have the opportunity once again to report on the current status of cardiovascular, pulmonary, and hematologic research. The media have reported extensively on research on the blood-borne infectious agents associated with acquired immunodeficiency syndrome (AIDS) and on advances in development of artificial devices for cardiac assistance or replacement. I shall comment on these more fully in my oral remarks but in this statement I wish particularly to discuss progress resulting from some new initiatives that are improving our understanding of basic processes and thus are contributing to the control and prevention of heart, lung, and blood diseases.

Magnitude of the Problem

To remind the Committee of the magnitude of the problems that challenge us, I will briefly reiterate the dimensions of the mortality and morbidity associated with the diseases within our Institute's purview. It is gratifying to be able to report a downward trend in mortality from cardiovascular diseases, a trend that has persisted during 15 of the last 16 years. Since 1968 the mortality rate from coronary heart disease has decreased 37 percent and that from stroke 52 percent. Despite these encouraging trends, diseases of the heart and blood vessels remain the number one killer of the American people. Also disappointing is the fact that diseases of the lung continue to escalate and that chronic obstructive lung disease is the most rapidly rising cause of death in this country. It affects one out of every 20 Americans. With regard to blood diseases the tragedy is that some (e.g., Cooley's anemia and sickle cell anemia) kill early in life while others contribute to many cardiovascular and pulmonary disorders. Moreover, the incidence of transfusion-transmitted hepatitis is between 7 and 10 percent among the more than 3 million Americans who are transfused each year with whole blood, red blood cells, platelets, or fresh-frozen plasma.

Frontiers in Basic Science

Beginning in September 1983 with the Institute's commemoration of its own 35th birthday and that of the American Heart Association, the Institute has held a series of conferences on "Frontiers in Basic Science that Relate to Heart, Lung, and Blood Diseases." These have served to disseminate the most recent advances by probing changes at the cellular, subcellular, and molecular level associated with normal metabolic and physiologic processes and their derangement in disease states. The most recent conference, in December 1984, emphasized the characteristics of the plasma membrane and its role as a site for receptors involved in physiological regulation of the cardiovascular, pulmonary, and blood systems. A conference scheduled for this year will address another physiologic interface; namely, the blood vessel wall. The interaction between the walls of blood vessels and the blood that traverses the vessels involves changes reflected in diseases of the cardiovascular, pulmonary, and blood systems. These conferences, which have brought together basic researchers and scientists concerned with the clinical aspects of heart, lung, and blood diseases, have generated an enthusiastic response and have had a positive impact in stimulating new initiatives that involve both fundamental and clinical disciplines.

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Basic research continues to provide major tools for meeting the challenges of clinical problems that confront us. Among "new frontiers" associated with outstanding success are investigations of biochemical genetics using sophisticated recombinant DNA and monoclonal antibody technologies. I would like to mention a few applications of these technologies to heart, lung, and blood diseases.

Clinical Applications of Basic Science

The application of molecular genetics to hypertension is of great interest because this disorder affects 60 million Americans, which is about 26 percent of our population. In this context, recent progress in the study of a substance that both relaxes smooth muscle and increases excretion of water and sodium is of great interest. Called "atrial natriuretic factor" (ANF), this substance has been purified from extracts of the atrium of the heart, and its synthesis has been shown to result from the action of a single gene, which has been cloned. ANF is now believed to be the product of granules in the atria of mammals. The granules were identified more than two decades ago but their function was not known. Through the use of cloned gene sequences, researchers have identified the structure of the ANF precursor. Hence, it is now possible to study how it affects normal blood pressure and whether it also contributes to the development of essential hypertension. Through insights into the role of such basic etiologic factors we anticipate coping more effectively with the problem of preventing hypertension. Recombinant DNA technology has also been applied to the problem of identifying the genetic abnormality that is the causal agent in cystic fibrosis (CF), which is an inherited disease with lethal pulmonary involvement, affecting one in 2,000 live births in this country. In addition, one in 20 white Americans are carriers of a single defective CF gene. They are potential transmitters of the disease, although only individuals inheriting two CF genes have the clinical manifestations of this fatal disorder. The availability of recombinant DNA technology, coupled with the recent identification of a large family that includes 22 kinship groups (sibships) with a number of members affected by CF, now provides a unique opportunity to map the position of the CF gene on a specific chromosome. This approach has been used successfully to identify the genetic marker of other inherited diseases, most notably the fatal Huntington's disease. Because CF is the most common lethal genetic disease that affects the white populations in United States and Europe, there is great interest in these new studies, which could lead to effective preventive measures. Identification of a defective gene by screening adults in the general population could be coupled with genetic counseling to minimize the frequency of transmission of CF genes when each parent is a carrier of only a single gene for cystic fibrosis.

The value of gene mapping has also been amply demonstrated in studies of sickle cell anemia, which can now be identified antenatally, using cells obtained by amniocentesis to study DNA sequences and pinpoint the mutation causing this disease.

Blood coagulation factor VIII which is absent or defective in the approximately 12,000 people in the United States who suffer from hemophilia A, must be replaced from exogenous sources to control this bleeding disorder. Until recently, spontaneous bleed-

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ing in these patients, and bleeding during surgical or dental procedures, could only be controlled by replacing the missing factor by transfusion using cryoprecipitate or lophilized concentrates. Unfortunately, this essential therapy carries with it the risk of exposure to viral hepatitis or other bloodborne viral diseases.

It is therefore gratifying to be able to report that recombinant DNA technology has recently been successfully applied to the production of factor VIII, and that the product has been shown to be biologically active. This achievement marks the cloning of the largest, most complex protein produced through genetic engineering. Although it may require two or more years to develop and clinically test this product, the achievement of a laboratory produced clotting factor is of great importance because it should lead to a less hazardous and perhaps a less costly alternative to plasma-derived factor VIII.

Concurrent with these and numerous other promising fundamental investigations are innovative approaches to the problems of diagnosis and treatment. Some examples relative to heart, lung, and blood diseases are commented upon below.

Advances in Diagnosis and Therapy

Lasers have unique and diverse properties that have amply proven their value in ophthalmologic practice and are now being extensively investigated for their applications to a variety of problems encountered in cardiovascular research. Properties of lasers -- such as frequency, intensity, duration of light emission, and the size of the spot produced -- can be varied. Because such changes result in differences in the depth of penetration and photodynamic effects on tissues, lasers with a variety of different characterstics are being developed. Lasers with variable frequencies are being evaluated for use in angioplasty, in which the lumen of a blocked artery is enlarged by removal of excessive lipoprotein and other plaque deposits. A carbon dioxide laser, in which the depth of tissue vaporization can be controlled, has been used effectively as a surgical blade for excising excess, overgrown heart muscle when correcting asymmetric septal hypertrophy. This carries less risk to the conduction system than other procedures. Similar instruments may sometimes facilitate repair of heart valves instead of requiring their replacement. Laser technology has also been utilized in fundamental studies, such as the microscopic observation of subcellular organelles in normal muscles and under abnormal conditions similar to those that affect the cardiovascular system. In experimental approaches, laser technology is also being examined in conjunction with studies of fiberoptic and computer technologies.

Innovative new technologies used to diagnose and treat various types of emboli are relevant to the problems of heart and lung as well as blood research. Currently, diagnosis of pulmonary embolism and its precursor deep vein thrombosis (DVT) depends on ventilation-perfusion scanning and angiography, which are techniques that have certain shortcomings. They lack sensitivity and specificity, and more importantly, are invasive procedures. Because of these diagnostic difficulties, there are problems in making an accurate determination of the incidence of DVT and the extent of pulmonary

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embolism. However, it is estimated that as many as 50,000 deaths in hospitals each year may be caused by pulmonary embolism, the number of episodes of pulmonary embolism among hospitalized patients in the USA approximates 500,000 per annum, and several times that number develop DVT. Clearly, the accuracy of diagnosis is of great importance in managing these disorders. It is encouraging to note that a new imaging technique being developed does not have the disadvantages of current diagnostic procedures. It depends on the use of monoclonal antibodies that are highly specific for an antigenic site on the fibrin component of the clot, and that do not react with the fibrin precursor (fibrinogen). In studies of femoral vein thrombosis in animal models, the thrombi accumulate large amounts of the radiolabelled antibody, and it is possible to image the clots from 4 to 48 hours after injecting the antibody.

These studies indicate that detection of deep vein thrombosis is possible with this technique. Further studies will address the application of this method to detect emboli in the lung.

Two drugs to dissolve arterial and venous clots have been licensed in this country. However, these agents, urokinase (UK) and streptokinase (SK), have characteristics that make them unacceptable for routine care, although they may be lifesaving in emergency situations. Streptokinase, when administered via a catheter, will dissolve a clot in a coronary artery within an hour. But it must be administered on short notice, and many hospitals lack the necessary equipment and trained personnel. If, as an alternative, SK is administered intravenously in large doses it may disturb the body's clotting mechanism and lead to bleeding. Because both SK and UK can upset clotting mechanisms in the body, they are now being studied in modified forms that seem to avoid the risk of bleeding associated with those now in use. A newer, quite promising agent is tissue-type plasminogen activator (tPA), which is an enzyme that occurs naturally in the body but which can be derived synthetically by recombinant techniques. This activator is undergoing clinical tests to determine whether it can minimize the damage due to a heart attack while not affecting clotting elsewhere in the body.

Conclusion

Finally, I would like to reaffirm our commitment to a balanced program that encompasses a large basic research effort through investigator-initiated research; clinical research that applies the findings of research to clinical investigation via our multidisciplinary centers program, and a demonstration and education program that transmits research findings to health professionals and the American public.

Mr. Chairman, the 1986 budget request for this Institute is $775,254,000, a decrease of $28,341,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985 this Institute will fund 727 new and competing grants of which 73 will receive 3 years of support. In addition, we will fund 57 centers, of which 2 will receive 2 years of support.

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Senator WEICKER. I read about the question before of new advance insofar as dissolving of blood clots. Is that something you can tell me a little more about?

Dr. LENFANT. Yes, indeed. It is a study that was reported just last week at the American College of Cardiology meeting held on the west coast. It consists of injecting a compound that is produced by recombinant DNA technology into a peripheral vein. When the compound called tissue plasminogen activator reaches the coronary arteries, it literally dissolves the clots that obstruct them. The results, which will be published in a couple of weeks in the scientific literature, show that nearly 70 percent of the patients receiving this compound will have their coronary arteries cleared in contrast to only 30 or 35 percent when using other products. It is a very significant advance.

As you know, Mr. Chairman, there are about 650,000 coronary obstructions that are——

Senator WEICKER [interposing]. How many?

Dr. LENFANT. Approximately 650,000 per year. So if the preliminary results coming from this study are confirmed, it will be a very significant advance, a major impact in terms of public health.

Senator WEICKER. I gather also from reading the article the hope is that persons might even be able to carry this with them on their person?

Dr. LENFANT. Well, I hadn't heard about that. It was probably an overenthusiastic reporter who wrote about it. The situation is as follows: Today if somebody has a heart attack, that person should be taken very quickly to a hospital that specializes in cardiology and that also has an intensive care unit. However, with the new drug, the expectation is that practicing physicians can administer it and basically treat the patient at home. What I am saying is that when there is any evidence of sudden coronary obstruction, the physician can inject the product, and immediately recreate passage in the coronary arteries and then later take the patient to the hospital for further examination and treatment. It is a very significant advance.

Senator WEICKER. How long before this goes into general use? What are we talking about timewise?

Dr. LENFANT. The study that you are talking about is phase I of the clinical study and phase II will be initiated very soon by the Institute. Although we expect that the drug will be used before phase II is completed, we believe that phase II is needed and, in fact, is very important in order to assess the long-term efficacy of the treatment, as well as to assure that there are no long-term complications with the drug.

The drug has not been approved by the FDA. The study I mentioned was possible because of a special authorization of the FDA to the National Heart, Lung, and Blood Institute in order to conduct phase I.

I think that within 1 year to 18 months the drug will be on the market, but the final evaluation will not be before a year, maybe two, or even longer.

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Senator WEICKER. Just repeat for me, what was the NIH role in this?

Dr. LENFANT. We initiated the study, we supported it, and we were pleased to report on it just 2 weeks ago. The staff of the Institute conducted and managed the study in cooperation with seven or eight institutions.

Senator WEICKER. A figure of 650,000 is staggering in terms of the economic, not just a matter of life and death, but an economic impact.

Dr. LENFANT. There is no question, Mr. Chairman; each year in this country we have about 1,250,000 people who have a heart attack, either a first one or second or third one. Of these heart attacks, one-half are due to a blood clot in the coronary arteries. That is the 650,000 that I mentioned. Your assessment is correct; it is staggering.

CHOLESTEROL AND DIET

Senator WEICKER. What further progress is being made? I know last year we concentrated a great deal of our discussion, not just your Institute—cancer and other institutions—on the matter of preventive medicine, nutrition, et cetera. Certainly that plays an important role, it seems to me, in the matters you are interested in.

Dr. LENFANT. Indeed. I am sure almost each week you see in the press or on TV or hear on the radio some report about a consensus conference that we held earlier this year. The purpose of the conference was related to blood cholesterol level and how it could and should be lowered in order to decrease the risk of heart attack.

The whole thing revolves around nutrition. There is no question that the blood cholesterol level is very much related to the ingestion of fat.

The conference came up with a number of recommendations which we are beginning to implement and to disseminate to the practicing physicians and the public as well. The most important recommendation which came from this conference, and I think it is supported by many experts, is that the American people would do well to pay attention to their diet and to modify it when necessary.

CURRENT SERVICES

Senator WEICKER. You are forecasting a 2.4-percent increase in your fiscal year 1986 budget based on borrowing $12 million from your fiscal year 1985 budget. How much money will be required in fiscal year 1986 to allow your Institute to function at the congressionally mandated fiscal year 1985 levels, 6,500 new and continuing NIH grants overall?

Dr. LENFANT. I think you are asking what we call the current services estimate. Based on the 1985 appropriation, that level, Mr. Chairman, would be $885 million.

HYPERTENSION SCOR

Senator WEICKER. I understand one of the most successful prevention programs is in the area of hypertension. You have a very successful Specialized Center Program in hypertension.

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I am told that this program is in jeopardy of being drastically reduced in fiscal year 1986. Is that correct?

Dr. LENFANT. Within the President's budget, the answer is yes.

Senator WEICKER. How many Americans suffer from high blood pressure?

Dr. LENFANT. About 60 million people; one-quarter of the U.S. population.

Senator WEICKER. A lot of people. What is this Specialized Center Program?

Dr. LENFANT. It is a program which has some very unique characteristics. Basically the criteria of this type of center is to bring basic fundamental research together with clinical research, and the ultimate goal is to have the iterative process between these two types of research, so that the result of the basic research can be brought to the bedside. In fact, Mr. Chairman, the work that we were talking about earlier, that relative to the drug that clears up the coronary arteries, was done in some of our specialized centers of research.

In our Institute, at the present time, we have 57 centers, 5 of them in the hypertension category.

Senator WEICKER. How much money is expected to be saved out of this year's budget request vis-a-vis——

Dr. LENFANT [interposing]. We will be using $3 million of this year's appropriation to fund 2 of our centers for 2 years instead of funding 59 as was expected on the basis of the appropriation. We will be funding 57, 2 of them for 2 years.

Senator WEICKER. So the dollars saved?

Dr. LENFANT. The amount is about $3 million saved this year to pay for next year's centers.

Senator WEICKER. Again, I don't know what the economic impact is of 60 million Americans that have high blood pressure. It seems to me the figures related in a dollar amount to the 60 million.

Dr. LENFANT. Well, I cannot tell for hypertension alone; however, all cardiovascular diseases, including hypertensive diseases, cost this country about $60 billion a year.

Senator WEICKER. This is the point to be made throughout these hearings, that for whatever is achieved in these few millions of dollars by way of savings now, there is just a tremendous cost to be paid in the outyears. It is not a real budget saving. This is not part of deficit reduction and, indeed, it is going to saddle us with deficits in the future, trying to get out of these problems. I would say this is a good example of one that is headed in the right direction.

Dr. LENFANT. I wonder, Mr. Chairman, if I could tell you about a case in point which will illustrate, perhaps, what you are talking about. You may have read in the newspapers a couple of weeks ago some articles about a new drug that is going to save the lives of premature babies. Let me tell you about this story. The drug in question is Indomethacin; 2 or 3 weeks ago it was approved by the FDA for the treatment of a congenital defect characterized by the nonclosing of a chan-

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nel between two arteries in the chest. If this channel is not closed at birth, there are some very serious complications that are lethal. In the past, the treatment was surgical and the cost of the surgery about $10,000. In the United States there are perhaps 16,000 to 20,000 infants who are born each year with this congenital defect.

The medical treatment that was announced 2 or 3 weeks ago is just as effective as surgery. It cost $40 to $50 per child and, therefore, the cost would be $800,000 for all of these infants, all 20,000 of them, as compared to $200 million using the surgical treatment. Our Institute was very instrumental in this advance; in fact, we conducted the basic research, the clinical research, and the evaluation of the treatment. Our investment has been $10 million over 12 years.

Senator WEICKER. $10 million over 12 years. What do you estimate the surgical costs are?

Dr. LENFANT. $200 million a year for the surgical treatment and $800,000 a year for the medical treatment.

Senator WEICKER. I notice my good friend Senator Byrd has joined us. I know he has many duties on the floor. Senator Byrd, sir, if you care to inquire of Dr. Wyngaarden of NIH or Dr. Lenfant of the Heart Institute. The staff informs me you have a particular question directed to Dr. DeVita. If you would like to do that, I will have Dr. DeVita come forward.

Senator BYRD. Thank you very much.

Senator WEICKER. Dr. DeVita, why don't you step in here a minute. I am sorry we are going to go out of order.

Senator BYRD. I apologize.

Senator WEICKER. My Democratic friends have a lot of problems on the floor. I don't want to add to them. [Laughter.]

Senator BYRD. Thank you. I wish all of my Democratic friends would view my situation with as much concern as the chairman. [Laughter.]

WEST VIRGINIA CANCER CENTER

Well, Dr. DeVita, of course, I have been very supportive of the Cancer Institute and the other Institutes over a period of a quarter of a century, as you know, on the Appropriations Committee. Senator Weicker and I wrote to you on January 31 of this year with regard to language that was included in the fiscal year 1985 appropriations bill for Labor, Health and Human Services, Education and Related Agencies authorizing the Construction Grants Program and the accompanying report language directing that $4.5 million was to be used for the Mary Babb Randolph Cancer Center at West Virginia University.

I have your response in which you stated, "The Institute is aware of congressional intent in this area. Inasmuch as Congress intended this $4.5 million be used for the Mary Babb Randolph Cancer Center," I assume that you are saying that you recognize this as being the intent of the Congress and that it was our intent that those moneys be utilized for and earmarked for that cancer center at West Virginia University in Morgantown; am I correct?

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Dr. DEVITA. Yes, sir, we recognize that, and the university has, in fact, put together a grant. The grant has been submitted and last Thursday and Friday a team of scientists from inside and outside the Institute went down to West Virginia and worked with them and began the first step in the review process to construct the program. It is going along very well.

Senator BYRD. How did the visit go?

Dr. DEVITA. I think it went along quite well. I heard just early reports of it. It is still in review.

Senator BYRD. Do you have the money available to fund that center at the full $4.5 million as provided in the fiscal year 1985 bill?

Dr. DEVITA. Yes; we do. The money is in the appropriations.

Senator BYRD. Should I anticipate any difficulty in regard to these moneys being used in accordance with congressional intent?

Dr. DEVITA. I will have no difficulty personally, but there is one difficulty perhaps that could be anticipated. That is, since the language did not have the effect of law, I am legally bound by the National Cancer Advisory Board's approval of the ultimate grant. I have no reason to expect it will not happen, but if they do not approve it I am not able to override that disapproval. We will continue to work very closely with them and at this point in time, I don't anticipate difficulties. I am not sure what the exact amount of dollars is. That would depend on the peer review system itself and the university's impression of it. That is the only difficulty I can anticipate.

Senator BYRD. When would you anticipate the outcome of the peer review?

Dr. DEVITA. It goes to full committee on the 26th of this month and will go to the May meeting of the National Cancer Advisory Board.

Senator BYRD. Mr. Chairman, I am not entirely satisfied with the answer, but Dr. DeVita does realize this was the intent of the Congress; it was in the Senate report, and he does not anticipate any problem with the earmarking and utilization of these moneys for the Mary Babb Randolph Cancer Institute at Morgantown.

Dr. DEVITA. As I say, Senator, we have been working with the University of West Virginia very closely for a number of years. They have been planning the project as long ago as 1972. Our staff has been working with them trying to develop the plans so they would have a functional center. I believe the fact the site visit went well last week is an indication we both made some progress. Our intention is to lean to the direction of your desires but must follow the procedure to a certain extent, but I don't anticipate any difficulty.

Senator BYRD. Very well. I want to thank you, Mr. Chairman, for the support you have given to this project. It is, of course, valuable and we in West Virginia recognize the support you gave us and the importance of that support. I may continue to need it. I know you will always be fair in your considerations of our problems and our requests. We will be following this with interest, Doctor, and if we feel we have to put something else into writing, we will not be reluctant to do that. [Laughter.]

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Thank you very much.

Dr. DEVITA. I think the National Cancer Advisory Board understands that.

Senator BYRD. I want to thank you, too, for the cooperation that has been given to the university in approaching the application. We are not unmindful of that. I personally thank you.

Senator WEICKER. Thank you very much, Senator.

What I would like to do now, I have asked questions of Dr. Lenfant. I have more I want to ask. Senator Proxmire has rejoined us. He had to go to the floor. Dr. Wyngaarden is still here, Senator, so why don't I turn it over to the distinguished Senator from Wisconsin.

BEHAVIOR RESEARCH

Senator PROXMIRE. Dr. Wyngaarden, as these hearings progress, I plan to talk to the directors of various Institutes about social science awards that seem to me to have little relationship to biomedical research. I refer to such activities as studying family event histories of the high school class of 1972, interracial friendiness among students, the formation of Haitian ethnic organizations and maintenance of typing skills in adulthood.

This particularly disturbs me because I see little evidence that you are looking into behavioral issues that could have a direct impact on health. For example, the Guttmacher Institute has recently came out with a very disturbing study on teenage pregnancies but I'm not aware of any NIH behavioral research into ways to influence sexual behavior so as to reduce such pregnancies. Another example is health and aging. Exercise could have a major influence here. But I don't know of any behavioral research into ways to motivate the elderly to exercise.

Have you supported behavioral research of that kind?

Dr. WYNGAARDEN. We support a large amount of behavior research. The largest amount is in two Institutes. The Aging Institute and the Child Health Institute, both of which have legitimate instructions to pursue work in those areas. Their efforts account for approximately one-half of our total NIH expenditures in the behavior and social research areas. Approximately $51 million in the Child Health Institute and nearly $21 million in the Aging Institute in 1985. The specific projects are not known to me personally, but I am certain the directors will be willing to discuss those with you.

Senator PROXMIRE. I would appreciate getting a response from the directors. It does seem some of the social science research you are supporting has far less promise than exercise and the elderly or the pregnancy problem. Teenage pregnancy, as you know, is a very serious problem. The most recent statistics indicate this country has far more serious difficulties with teenage pregnancies than other countries. Teenage pregnancies are about twice as common in this country.

I understand you have established an Interagency Planning Group on Health and Behavior?

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Dr. WYNGAARDEN. Yes.

Senator PROXMIRE. Has that group been permitted to develop requests for proposals that would alert the research community regarding what NIH considers the most promising opportunities for behavioral studies in biomedical areas, and has a special study section been formed to review such proposals?

Dr. WYNGAARDEN. We have study sections already constituted to consider proposals in the behavioral research category.

Senator PROXMIRE. Can we get a cross-Institute focus on behavioral studies? Wouldn't it be useful if we could get that focus?

Dr. WYNGAARDEN. Yes; it would be. We have a great deal of inter-Institute communication on the behavior science area, and I will be happy to look into that.

CHOLESTEROL AND DIET

Senator PROXMIRE. As you may recall, at last year's hearing we discussed diet as a means of reducing cholesterol levels. You commented that:

> Unfortunately it would take very severe dietary manipulations to have any effect on the cholesterol level * * * so dietary control of cholesterol is not very effective.

However, the National Heart, Lung, and Blood Institute had this to say in a response for last year's record on the use of diet to reduce cholesterol levels, and I quote:

> It is expected that the majority of the people—in the Lipid Research Clinics Trial—could be treated with diet alone in view of its efficacy in lowering blood cholesterol levels, its safety, and its low cost compared with drug treatment.

These statements seem to be diametrically opposed. Which one should we accept?

Dr. WYNGAARDEN. If I may, sir, I would like to defer that to my colleague, Dr. Lenfant. He can give you the answer.

Senator PROXMIRE. Dr. Lenfant, the buck has been passed to you.

Dr. LENFANT. Well, I am not sure there is an absolute contradiction between these two statements, Senator. As I was mentioning a little earlier, just a few months ago we held a conference concerned with lowering blood cholesterol to prevent heart disease. The conference was a consensus conference. By the end of 2 days, a fairly good consensus had been reached. Nearly all the recommendations that came from that conference concerned the efficacy and applicability of diet modification to reduce blood cholesterol levels in the American people.

For instance, one of the recommendations that was made was to reduce the fat intake to no more than 30 percent of the caloric needs. This is a modest decrease, from 40 percent, which is the current usual American diet, in other words, a 25-percent reduction.

One other recommendation was to limit the absorption of the so-called saturated fats, which are animal fats, to no more than 10 percent of the daily caloric needs, and to increase polyunsaturated fats but to no more than 10 percent of the daily caloric needs.

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Basically, the modification in diet that was recommended by this conference is not in contradiction of what was stated last year.

Senator PROXMIRE. Well, is diet considered a satisfactory alternative to the use of drugs?

Dr. LENFANT. It is certainly the first alternative.

Senator PROXMIRE. Then you would not agree with the statement that dietary control of cholesterol is not very effective?

Dr. WYNGAARDEN. It depends on the degree of elevation.

Dr. LENFANT. That is correct. It depends on the degree of elevation. If you have somebody who has a cholesterol level of 600 milligrams, which is nearly three times as much as it should be, the expectation of reducing that level by diet alone is wishful thinking.

Senator PROXMIRE. Isn't that a relatively rare instance? Don't the overwhelming majority of people have a much lower cholesterol level; wouldn't they be benefited by a diet change to lower their cholesterol concentration and, therefore, wouldn't the incidence of heart disease for most of the population be sharply affected if we could persuade people to be conscious of their eating habits?

Dr. LENFANT. No question about it. In this country, 40 percent, nearly one-half, of all the heart attacks are occurring in people who have a level of cholesterol that is in the 25th highest percentile of the blood cholesterol distribution curve. This is where you find the most heart attacks.

Senator PROXMIRE. For those that wouldn't be adequately treated through a change in diet you could use drug treatment.

Dr. LENFANT. That's correct.

Senator PROXMIRE. But for others, diet might be——

Dr. LENFANT [interposing]. Those who are considered moderate.

SMOKING AND HEALTH

Senator PROXMIRE. Dr. Wyngaarden, as we both know, smoking is one of the greatest killers on the American health scene today. At the same time, NIH will have spent $56 million over the 7-year period ending in fiscal year 1985 on smoking and behavior research. As I understand it, this research has nothing to do with the physical effects of smoking but is intended to explore ways in which people can be motivated not to smoke. Can you tell us what this investment has produced in the way of innovative procedures to reduce the incidence of smoking?

Dr. WYNGAARDEN. As part of the multiple risk factor trial for coronary heart diseases, there was an intensive effort to monitor the life style adjustments of certain patients in the study group, which included smoking, and there is significant success in that group.

Senator PROXMIRE. What specific innovative procedures were introduced to achieve this change?

Dr. WYNGAARDEN. It had to do with the monitoring of the care of those patients by physicians in study programs and reinforcing knowledge through behavior changes, including smoking in the one group,

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and leaving the other group to withstanding therapy only. Therapy also changed during that decade as also general awareness developed about the advantages of weight control, exercising, and control of smoking.

Senator PROXMIRE. For the record, could you tell us what procedures have been found particularly useful in reducing the incidence of smoking?

Dr. WYNGAARDEN. Yes, sir.

Senator PROXMIRE. How much do you plan to spend on smoking and behavior research in the coming fiscal year?

Dr. WYNGAARDEN. In 1985 we estimate that $32.3 million will be spent.

Senator PROXMIRE. I gather you have a multiyear smoking research budget strategy. How much do you plan to spend in total over the next few years?

Dr. WYNGAARDEN. With the estimated $33.1 million we plan to spend in 1986, the 2-year total will be $65.4 million.

[The information follows:]

SMOKING AND MRFIT

One of the gratifying outcomes of the MRFIT study was the quit rate for smokers in the special intervention group. MRFIT achieved a 40-percent abstinence rate at 48 months. These rates are the most encouraging results of any well-designed study reported—approximately 50 percent better than the best previous results obtained by the use of the individual methods available at the time the MRFIT program was developed.

A specific factor distinguishing the MRFIT program from other smoking cessation programs was the continual, uninterrupted contact with participants after initial intervention. MRFIT cessation data strongly suggest that this continual contact plays an important role in achieving, maintaining, and for certain individuals that frequently return to the smoking habit, reachieving nonsmoking status. The problem is not how to get people to stop smoking, but how to get people to remain nonsmokers once they quit.

The MRFIT cessation rate dramatically focuses attention on the interpersonal factors embodied by the continued contact of the MRFIT program which apparently have contributed to the improved results obtained from a rather diverse melange of techniques that had never before yielded such high long-term quit rates. For an additional number of smokers, this factor has apparently made a difference in their ability to achieve abstinence. That is, while other studies employing a wide variety of behavioral, educational, and cognitive techniques yielded about 30 percent quit rate at the end of 1 year, MRFIT showed quit rates in excess of 40 percent at the end of 4 years.

Among the many approaches used in the MRFIT smoking cessation program was a series of so-called trigger films that were employed in individual of group counseling. Many MRFIT investigators felt these films were particularly helpful in reaching that 40-percent abstinence rate. Although the films were several years old, Institute staff felt that they had considerable value as a counseling tool. Along with some MRFIT investigators, our staff developed a discussion guide for counselors and health professionals to accompany the films. The initial reaction to this smoking cessation package was quite favorable. We are now promoting the package through a variety of channels and distributing it through the National Audiovisual Center. The response continues to be positive. And, I am happy to report that during the past year these MRFIT films won the award for "Best of the Film Festival" of the American Association for Counseling and Development and another award for "outstanding audiovisual production" from the National Association of Government Communicators.

The MRFIT results enable us to identify subgroups in a heterogeneous smoking population. Already identified are (a) those who can quit with little or no assistance; (b) those who require a special program or technique mediated or provided by experts

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(the long-term successes from the formal cigarette smoking cessation programs); (c) those who are unable to quit with any of the current programs (the hard core of non-quitters or quitter then quick recidivists); (d) those who can achieve and maintain abstinence only while in continued long-term contact with a formal cigarette cessation program. The MRFIT experience has not discovered the panacea but has identified an approach that appreciably improves cigarette smoking cessation efforts and reaches a group that previously failed to quit smoking.

SMOKING AND BEHAVIOR RESEARCH PROGRAM FUNDING

Senator PROXMIRE. I notice your smoking and behavior research program funds projects through three different institutes. In fiscal year 1985, for example, the Cancer Institute is expected to spend $9,584,000, the Heart Institute $5,298,000 and the Institute of Child Health and Human Development $1,300,000. Wouldn't it be more efficient to run this program out of just one Institute?

Dr. WYNGAARDEN. I think to control smoking is integral to the matter of incidence of cancer. It certainly is relevant to the incidence of heart disease, and it is a behavioral problem that begins in teenage. It seems to me the Institute has a legitimate interest in funding——

Senator PROXMIRE [interposing]. I understand that, but because it is one specific human habit, it would seem to me that a concentration of your resources in one of the Institutes—maybe the Cancer Institute, because that is where you have the most money—might be more cost effective.

Dr. WYNGAARDEN. We will look at that to see if this is advantageous.

BYPASS SURGERY

Senator PROXMIRE. You tell me, Mr. Chairman, when my time is up. I have two or three questions for Dr. Lenfant.

Last year you told the subcommittee in a response for the record that coronary bypass surgery in those with mild heart disease symptoms does not appear to prolong an already excellent survival outlook in patients treated medically. You went on to say that in 40 percent of all bypass patients the grafts begin to close up after 10 years and that the second operation is more risky.

Has there been any measurable reduction in the use of bypass surgery as a result of these findings?

Dr. LENFANT. I looked into that before coming here today and I have two answers. One answer says yes, there has been a decrease in the number since last year and the other one says, no but the number has not increased, which is just as significant as the first answer because for the last 10 years the number has increased about 10 percent each year.

Senator PROXMIRE. Let's see, I am trying to get an interpretation of that statement. [Laughter.]

You have arrested the rate of increase?

Dr. LENFANT. That's it.

Senator PROXMIRE. Are you studying any other surgical procedures to determine if they are overutilized, or do you plan to do so in 1986?

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Dr. LENFANT. No.

Senator PROXMIRE. You aren't?

Dr. LENFANT. No; I don't know what surgical procedure you are thinking about. I am not aware of any surgical procedure——

ARTIFICIAL HEART DEVICES

Senator PROXMIRE [interposing]. I have no particular procedure in mind.

Dr. Lenfant, last year you told the subcommittee that you planned to spend between $8 and $9 million on the development of an implantable electrically powered ventricular assist device with a demonstrated 2-year reliability. How much do you plan to spend on that program next year?

Dr. LENFANT. It will be in the same order.

Senator PROXMIRE. Can you give us a rough estimate of the long-term costs of the program?

Dr. LENFANT. This program was begun in 1961. It is a complicated program that includes the device that you are speaking of, as well as the artificial heart, such as the Schroeder or Barney Clark type of device. It has cost approximately $179 million since 1961. The current rate of expenditure is on the order of $8 million per year.

Senator PROXMIRE. Do you expect these costs to go on indefinitely?

Dr. LENFANT. No; this cost is for the development. None of the costs are for the human application.

Senator PROXMIRE. When do you think the development will be completed?

Dr. LENFANT. For the temporary device, I would say within 3 or 4 years we will be able to recommend a device with a great deal of reliability, as well as a manageable device from the viewpoint of the patient.

Senator PROXMIRE. You indicated the system would have a demonstrated 2-year reliability. If the assist device were refined to the point that it could be used on a human patient, what further steps would be taken to extend life at the end of the 2-year period of reliability?

Dr. LENFANT. The test that is being given now is a bench test. The artificial heart, or device I should say, is made to pump blood in and out for 2 years. Once we know that a device can operate for such a period of time without failure, then it can be used in animals and then human application can begin.

I should tell you, Mr. Proxmire, this program is seeking to obtain a better, more manageable, more reliable and more economical device. However, during the last 10 or 15 years, nearly 300 people in this country have had their life extended for some period of time using similar devices, and the rate of success is on the order of 25 percent.

Senator PROXMIRE. If such a device were made available to all who needed it, what would be the annual costs?

Dr. LENFANT. Our estimate is that very soon there will be between 10,000 to 20,000 people each year who would require such a device for some period of time. Today these devices are very expensive, primarily,

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because very few are produced. My expectation is that, within a few years, these devices will be less expensive than they are now. How much less that is going to be, I cannot give you an answer at this time, but I know it would be less expensive than it is today.

Senator PROXMIRE. Do you believe that the cost of such a device would be reasonable, not so excessive as to be prohibitive?

Dr. LENFANT. Senator Proxmire, the answer to your question is tied to what we were discussing earlier. Some patients who have received a first coronary bypass are now coming back 10 years later for the second one. These are the people who are going to be very difficult to wean from the heart-lung machine that is required for the operation; these are the people who will need to be supported by a system for some period of time before they can be weaned from the device. This is where the device that you are referring to will become useful.

HYPERTENSION

Senator PROXMIRE. On February 4, a UPI wire story made reference to a Mississippi study of 496 people whose hypertension has been controlled by medicine for at least 5 years. The study indicated that about three-quarters of the group could stop taking drugs without experiencing an increase in blood pressure by relying on weight loss and reduced salt intake to keep their blood pressure under control.

Was this an NIH-funded study and are you aware of its conclusions?

Dr. LENFANT. I am aware of it, and it was supported by NHLBI.

Senator PROXMIRE. I note that you are supporting a hypertension primary prevention trial to test the efficacy of nutritional intervention in individuals predisposed to the development of hypertension. Do you plan any comprehensive trials to determine the extent to which existing hypertension can be controlled through changes in life style?

Dr. LENFANT. As a matter of fact, this is one of the clinical trials which is listed for 1986.

CHOLESTEROL DRUGS

Senator PROXMIRE. As you may recall, last year we discussed the use of an expensive drug—cholestyramine, I believe—to lower blood cholesterol levels. I believe you said the drug would cost about $150 a month. That works out to $1,800 a year.

I understand that a team of your scientists has found a common antibiotic, neomycin, that can be effective in lowering cholesterol levels. I also understand that this drug is inexpensive.

Do you plan to conduct any clinical trials using neomycin?

Dr. LENFANT. I don't know of this particular report, but I will look into it and if there is some foundation to it——

Senator PROXMIRE [interposing]. Would you tell us if you can find out, what the yearly cost of the drug is?

Dr. LENFANT. You said neomycin?

Senator PROXMIRE. Neomycin.

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Dr. LENFANT. All right.

Senator PROXMIRE. n-e-o——

Dr. LENFANT [interposing]. Yes; I know how to spell it. [Laughter.]

Senator PROXMIRE. The report says that a common antibiotic, neomycin, safely lowers blood levels of cholesterol in patients who have abnormally high levels, according to a team of scientists at the National Institutes of Health, Bethesda.

Dr. LENFANT. I will have to look into that.

Senator PROXMIRE. I have one other question. Apparently your earlier trial of the use of cholestyramine to lower blood cholesterol levels showed no difference in the death rates between those that used the drug and those that didn't. The drug treated group had fewer heart attack deaths but tended to die more frequently in accidents or by their own hand.

Could these findings indicate that the drug has a depressive effect that might offset its benefits as a cholesterol-lowering agent?

Dr. LENFANT. That is a question which has been raised in some circles. There is no way we can attribute——

Senator PROXMIRE [interposing]. It looks like a pretty strong possibility.

Dr. LENFANT. It is, indeed, a very serious question which needs to be explored. In fact, we are exploring it in the sense that we are continuing to monitor the patients who were part of this study to see if continuation of the drug has any effect whatsoever on their behavior. But at this point in time we have no indication that substantiates this attribution.

Senator PROXMIRE. If you accept the argument that there is no difference in the death rate between those who used the drug and those that didn't.

Dr. LENFANT. In coronary heart attack?

Senator PROXMIRE. No, no difference in their survival rate. Some die of heart attacks and others commit suicide.

Dr. LENFANT. But the latter is a crisis; it has not contributed to the disease.

Senator PROXMIRE. You haven't had a sufficient number of cases to determine whether the violent deaths are coincidental.

Dr. LENFANT. In some of these violent deaths there were one or two suicides, but the rest were either homicides or street accidents and things of that nature.

Senator PROXMIRE. Thank you, Mr. Chairman.

OCCUPATIONAL DISEASE

Senator WEICKER. Thank you, Senator Proxmire.

During the past year, Dr. Lenfant, there have been a number of articles describing concern about exposure of people to asbestos in public buildings, such as airports, schools, and Government offices.

Is there a real threat from these types of exposures, and what is NHLBI doing about asbestos-related diseases?

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Dr. LENFANT. Mr. Chairman, asbestos is better known perhaps for causing cancer, but the fact is that asbestos is also responsible for a chronic lung diease which is called asbestosis; asbestosis is a disease which develops over a very long period of time, 20 to 30 years; therefore, it is very difficult to study because of the long latency. Once the disease is diagnosed, the patient is in very bad shape since it is not a curable disease. It manifests itself by obstructions of the airways and shortness of breath and, basically, the patients becoming so incapacitated that they have to stop working.

We have a large research program to study the mechanisms of that disease of which little is known at this time. The expectation is that perhaps in 10 to 15 years, there might be as many as 100,000 individuals who have confirmed asbestosis.

AIDS

Senator WEICKER. I have other questions for response for the record, but I do want to ask one last question which I realize spans a variety of institutes and disciplines. I don't believe, Dr. Wyngaarden, you want to get into this, but it certainly is some aspect of Dr. Lenfant. Where do we stand both in the progress of cure, prevention, in terms of funding, whether it is adequate or not, et cetera, relative to AIDS? This includes Dr. Lenfant, Dr. DeVita, you, Dr. Wyngaarden.

Dr. WYNGAARDEN. The total NIH effort in AIDS in 1985 is $61 million; that total in the Department is $96 million. The 1986 estimate for NIH is about $60 million, and the estimate for the Department is about $86 million. The reduction reflects the fact that the 1985 estimate includes substantial expenditures of one-time nature, such as facilities. The total research effort remains at least that of the 1985 budget. The NIH estimate comes down a little bit because we have been able to target some studies more directly. With the cloning of the virus and the definition of its sequence, we now can proceed very directly to analysis of portions of that genetic machinery that may be concerned with certain protein products that may be relevant to immune response. So the whole field is achieving a sharper definition.

I would say that the efforts are more sharply focused, but just as intensive as the previous year. We are currently in the process of reassessing the 1986 estimate. We will consult with each funding unit to see whether anything has substantially changed in their program that would require additional funds.

That information would feed into a resources group at the Department level where a supplemental request would be addressed. At the present, I have no indication that the funding level is not adequate.

Senator WEICKER. Dr. Lenfant, as far as your Institute is concerned?

Dr. LENFANT. Our commitment for this year, Mr. Chairman, is $10.1 million, and for next year our obligation will be $11.2 million. As you know, our part of the program described by Dr. Wyngaarden is related to the transmission of AIDS by blood transfusion.

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Senator WEICKER. What about this most recent test that has received all this publicity? Do you want to deliver your opinion of this matter? I think it has been very confusing to the public, I have to say to you right now. I really didn't understand what it is that is being done. This is a test, I gather——

Dr. LENFANT [interposing]. To notify people who have been exposed to the virus.

Senator WEICKER. Exposed to the virus. Does it tell those persons who have the virus?

Dr. LENFANT. No; if I may make a comparison, it is just like tuberculosis; you have heard of the skin test for tuberculosis. In this room, I would say one-half of the people would have a positive skin test but they don't have tuberculosis. All it means is at one time during their life they have been exposed to the tuberculosis bacillus. Same thing with this test.

Dr. WYNGAARDEN. Been exposed and have responded with the production of antibodies.

Dr. LENFANT. Yes.

Dr. WYNGAARDEN. We test for the antibodies. We presently don't have a mass screening procedure for the virus. That is a very detailed, elaborate research procedure.

Senator WEICKER. If the antibodies are being produced, then where is the problem as to finding the cure?

Dr. WYNGAARDEN. There is a great deal not known about whether those antibodies are protective. They are useful in determining that a person may be carrying the virus. At least the body has responded to its presence. It is a useful test for screening donated blood to exclude those samples that would be at risk. It does not prove the individual who has the antibody response has the virus or is continuing to incubate the disease. It is possible, but we cannot say that.

It is not a test for the disease. It is simply a test for prior exposure and reaction to the virus. And the tuberculin skin test is a good analogy. There are many people who have been exposed to tuberculosis, have had minimal infection, perhaps developed the antibodies, but never really became sick.

With the new test that we are advancing, we are now able to conduct studies that will teach us a great deal more about the natural history of this disease, and there is a lot to be learned. We don't know, for example, what the probability is of developing the disease, how many people may have the virus and handle it with their own immune system and destroy it and be perfectly well. A lot of questions need to be addressed.

Dr. LENFANT. One study supported by the Institute, will provide some answers. Before the test in question was available, we sampled blood from 200,000 donors and stored the blood. Now that the test is available, we are going to test these samples for antibodies; because these donors can be related to people who have received their blood, we

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hope to obtain a lot of new information with regard to the natural history of the disease.

Senator WEICKER. And the fear, as I gather, was that people wouldn't take the test because they wouldn't want to find out they had such exposure and such antibodies.

Dr. LENFANT. That is one of the most important issues. If a person receives the test and is found to be positive, this person may be improperly accused or alleged to have the disease known as AIDS and, of course, in view of the nature of this particular disease, it would create serious personal problems. So it is a very difficult issue. In addition, the people who donate blood now must sign an informed consent stating that there will be further confirmation or verification if the test result is positive. Therefore, the issue of confidentiality of that information becomes an even more important issue.

It has been a very difficult issue for all of us to resolve over the last few months.

Senator WEICKER. But am I correct, when I surmise from your statements that many of us in this room, in other words, could come out positive, if you will, on this test——

Dr. LENFANT [interposing]. No; I said that about tuberculosis exposure, not about AIDS. In fact, from some spot samples which have been done, I think that only 1 out of 100 people has been exposed to the AIDS virus.

Senator WEICKER. The fear is the stigmatization that comes from positive reaction to a test.

Dr. WYNGAARDEN. That is part of it. Also, people might use the blood bank mechanism for testing because it is one way of receiving an answer as to whether they might have been exposed. At present, the high-risk groups have complied voluntarily in not donating blood and that has helped to reduce the likelihood of a contaminated blood supply. There was concern that this trend might be reversed if the test were available, and no alternative mechanisms for testing were provided. The Public Health Service is financing the establishment of alternative testing sites around the country.

Senator WEICKER. Is it possible to do the same thing, the same test with the blood itself?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. With donated blood, is it possible to tell whether the blood is contaminated?

Dr. WYNGAARDEN. Yes; the test is done on the blood. It is not a skin test. The test is performed in the blood banks. It will also be established in nonblood bank sites, such as possibly Health Department laboratories and private laboratories.

Senator WEICKER. I gather we are talking about funding here that is just about level as to what it was last year?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Yet what is the incidence of the disease? Isn't it multiplying rather rapidly?

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Dr. WYNGAARDEN. It is increasing. In the February 25 estimate, there were 8,597 cases.

Senator WEICKER. How many were there 1 year ago?

Dr. WYNGAARDEN. Some 80 percent of those are since 1983.

Senator WEICKER. Eighty percent since 1983?

Dr. WYNGAARDEN. The incidence is about doubling each year.

Senator WEICKER. What is your prediction for 1 year from now?

Dr. WYNGAARDEN. We don't know, obviously. We anticipate that some of the recognition factors that have been well publicized over the last few years will begin to have an effect; that is, changes in sexual practice and behavior, such as those related to the bath house use in San Francisco, one example, may have an effect, but it will take time for that to appear because the incubation period may be 2, 3, or 4 years.

Senator WEICKER. Are you sure you have enough money for this problem? I realize that money is not the answer to everything.

Dr. WYNGAARDEN. We have given this a very high priority in the Department. We have shifted funds from some other activities to maintain the AIDS effort. Our present feeling——

Senator WEICKER [interposing]. Just on the subject of AIDS, your budget request, was that altered in any way by OMB, just on the AIDS matter?

Dr. WYNGAARDEN. In the 1986 budget?

Senator WEICKER. Yes.

Dr. WYNGAARDEN. Not to my knowledge.

Dr. LENFANT. That's correct. Our program requirement needs are in our budget.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I could really spend considerably more time. I am going to instruct my staff from now on not to have so many institutes in one morning. Again, we are running against the clock, and I will have the rest of my questions submitted for response for the record, as will be the questions of other Senators for response to the record.

Thank you very much, gentlemen.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

OMB DIRECTIVE

Question: Did you have the opportunity to respond to the OMB Directive before it was issued? Did you respond at all -- at any time?

Answer: The OMB decision to reduce the number of competing research project grants and centers in 1985 was transmitted to the NHLBI from Dr. Wyngaarden. We did not have an opportunity to comment on this approach prior to the OMB decision.

Question: The OMB Directive will reduce the number of continuing research awards by 89 -- is that correct? That means that 89 ongoing projects that already have spent hundreds of thousands of dollars, and have been judged valuable enough to be continued will stop. Am I correct? What happens to the research, the scientist, his technicians and his students?

Answer: The OMB decision, which reduced NHLBI's share of competing research project grants in total from 949 to 727, will reduce the number of competing renewal awards by 89: from 374 to 285. The estimated total cost associated with this reduction is $14,987,000. We are concerned about the possible impact on continuing the research effort associated with ongoing programs supported by the NHLBI, as well as the possibility that research teams will lose continuity. It is for these reasons that the NHLBI is reviewing these projects with great care and considering what options are available.

Question: Can you give us a description of the research projects that will not be continued and estimate for us what may be lost by this action.

Answer: Not all of the applications eligible for funding in 1985 have been reviewed and therefore we have not made final decisions regarding which particular applications will go unfunded. It is likely, however, that unfunded competing renewal applications would have supported research in several different areas. For example, projects in the Heart Program that will probably go unfunded include research relating to the clinical management of patients with myocardial infarction. In the Lung Program, projects in the area of chronic obstructive pulmonary disease are likely to go unfunded. In the Blood Program projects, that are likely to go unfunded include studies on the formation of blood clots in the arteries.

BUDGET

Question: You are forecasting a 2.4% increase in your FY 86 budget based on borrowing $12 million from your FY 1985 budget. How much money will be required in FY 1986 to allow your Institute to function at Congressionally mandated FY 1985 levels, i.e. 6,500 new and continuing NIH grants overall?

Answer: The Institute would require $885,556,000 in 1986 to maintain its program at the current services level permitted by the 1985 Appropriation.

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Question: How many new and continuing grants would be added to your FY 1986 request at these levels?

Answer: In 1985, funds for 949 new and competing research project grants were included in the Appropriation bill. If these grants were funded in 1985, our 1986 noncompeting commitments would increase by 278 over the 1,654 grants currently projected. In addition, the Institute would need to fund 268 more new and competing research project grants than the 681 proposed in the 1986 request to reach the 1985 Appropriation level of 949 new and competing grants.

FTEs VS. PROGRAM

Question: Your FY 1986 budget continues the trend of proposing reductions in full time equivalent employment despite Congressional concerns about the wisdom of this strategy. What is the FTE reduction proposed for the National Heart, Lung, and Blood Institute in fiscal year 1985 and 1986? What impact will these reductions have on conducting and monitoring complex research programs like clinical trials or sophisticated basic science research in your intramural research program?

Answer: The number of full time equivalent positions for our Institute in the 1985 appropriations bill was 875. This number has been reduced by 26 to 849 in the 1985 current estimate. In 1986, this number will be reduced by an additional 10 FTEs to a level of 839. We will be able to maintain ongoing programs with these reduced levels. The decreases will affect, however, our ability to implement new programs.

Question: This Committee has supported your request for Specialized Centers for Research. You are now proposing an FY 1986 budget that will support four fewer Centers than in FY 1985. Are these Centers an important mechanism in accomplishing your Institute's goals?

Answer: We are proposing to fund 55 centers in 1986, which with the 2 centers funded for 2 years in 1985 will maintain the number of centers at the 1984 and 1985 level. The Specialized Centers of Research (SCOR) programs constitute an important and integral component of the overall NHLBI research effort. They serve as an effective means of concentrating resources, facilities, and research personnel on high priority research topics and serve as an important mechanism in accomplishing Institute goals. The multidisciplinary nature of the individual SCORs, when coupled with the program emphasis on network coordination, provides the Institute with a valuable complement to its portfolio of investigator-initiated research projects.

Question: Describe one of these Centers and tell us what it does.

Answer: The typical individual SCOR consists of a number of specific research projects and a number of central "core" units that provide laboratory, data processing, and other necessary research services and administrative services for the research projects. The research efforts of the centers include projects

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with a basic science emphasis and projects with a clinical research focus to ensure that advances in the basic sciences are rapidly translated into clinical applications and that clinical needs will provide a direction for the basic science.

Question: What Centers will not be funded in FY 1986?

Answer: As an immediate result of reducing the number of centers for 1985 from 59 to 57, the Institute will not make the two planned centers awards to establish a new SCOR program in transfusion medicine. The funds originally allocated for the transfusion centers will instead be used to fund two other existing centers for an additional year.

The reduction to 55 center awards in 1986 means that the Institute will face a very difficult choice. Both the hypertension and thrombosis SCOR programs are due for renewal in 1986. There are presently five hypertension and four thrombosis centers. If the Institute elects to delay again its implementation of the new SCOR program in transfusion medicine, then the reduction in center numbers will leave the total number of funded centers constant. However, if the Institute chooses to begin its transfusion medicine SCOR program then reductions will be required in one or both of the two programs due for renewal.

Question: How will the proposed reduction in Centers impact on other programs of the Institute? For example, will investigators from the closed Centers increase the number applying for individual grants?

Answer: There will be no direct financial effect on the other NHLBI programs. However, Specialized Centers of Research programs serve as a stimulus to the initiation and/or acceleration of independent research activity in the program area. Delay in initiating the transfusion medicine SCOR program may reduce investigator-initiated research activity in transfusion medicine. On the other hand, initiation of the Transfusion Medicine SCORs in 1986 would also require reductions in the numbers of hypertension and/or thrombosis SCORs, and reducing the number of active SCORs in hypertension and/or thrombosis would also reduce the amount of clinically oriented research in those areas.

Unfunded SCORs contain subprojects that may be submitted for funding as research project grants. Presently there are 5 funded hypertension SCORs that include an average of 10 subprojects each. Reducing the number of funded hypertension SCORs to 3 means that we can expect at least 20 more high quality research project grant applications. At the February 1985 meeting of the National Heart, Lung, and Blood Advisory Council, SCOR applications with excellent priority scores included a total of 77 subprojects, 32 of which will be supported. The remaining 45 subprojects, all of excellent quality, are likely to appear in future competitions for research project grant support.

Question: Can you provide me with areas in which research opportunities will be lost or significantly delayed by the lack of appropriate growth in the centers' program?

Answer: The NHLBI-developed Specialized Centers of Research

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(SCOR) programs are especially useful mechanisms for significantly accelerating research in targeted areas where coordinated, multidisciplinary efforts are likely to produce rapid clinical applications of basic science advances. The Institute has identified several important research areas in addition to transfusion medicine where the SCOR mechanism would be particularly applicable. Research in nutrition and its relation to diseases within the Institute's mandate requires multidisciplinary teams and close collaboration among basic scientists and clinical investigators. Similar conditions are required for advances to be realized in the prevention, diagnosis and treatment of dysrhythmia and sudden death, pediatric heart disease, pediatric anemia, hemophilia, aperipheral vascular disease, deep vein thrombosis and pulmonary embolism. Each of these areas is an important medical problem and is, therefore, a potential subject for a future SCOR program.

HYPERTENSION VS. BUDGET

Question: I understand that one of the most successful prevention programs is in the area of hypertension. The NHLBI has a very successful Specialized Center Program in Hypertension. I am told that this program is in jeopardy of being drastically reduced in FY 1986. Is this true?

Answer: The Specialized Centers of Research in hypertension exemplify a very successful research program that combines elements of basic clinical research. The Institute will decrease the amount of support it provides for this program but by a relatively modest amount.

Question: How many Americans suffer from high blood pressure?

Answer: Approximately 60 million Americans have hypertension.

CENTERS

Question: Please tell me how as a respected physician you can defend a budget that guts a program that has potential benefits for 60 million Americans?

Answer: The reduction proposed does adversely affect this program but permits most research activities to continue. In addition, the overall Institute research program in hypertension totals approximately $100 million.

Question: How much money is scheduled to be saved by reducing the Specialized Center program in hypertension?

Answer: Five such centers are currently funded at an estimated 1985 total cost of $8,315,000. If five centers were to be supported in 1986 the projected total cost would be $9,986,000. The present plan is to fund three prestigious centers at an estimated 1986 cost of $7,210,000. Relative to the 1985 budget for this program, this would result in a savings of $1,105,000.

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RESEARCH VS. BUDGET

Question: I have been reading about recently developed alternatives to cardiac surgery in the treatment of coronary artery disease. Can you describe the new techniques?

Answer: I believe the procedure to which you refer is percutaneous transluminal coronary angioplasty (PTCA). An inflatable balloon attached to the end of a catheter is placed across a narrowing in a coronary artery; the balloon is inflated and the narrowing is thus dilated. This procedure was first performed in September 1977. The balloon catheters have been refined substantially, and many cardiologists have been trained in this technique since 1977.

Experienced teams can now successfully dilate single artery narrowings in more than 90 percent of cases with low risk of complications. The mortality rate is less than 1 percent, and the risk of heart attack and/or need for emergency coronary bypass surgery is less than 5 percent. A major problem with this technique is that 1/4 to 1/3 of successfully dilated patients require a second dilatation because of recurrence of the narrowing 6 months to 1 year following the procedure. A second major unresolved issue is whether this procedure can be used in patients with multiple vessel coronary disease as a means of deferring coronary artery bypass graft surgery.

Question: How will these new techniques affect the cost of health care?

Answer: A formal comparison of costs between coronary artery bypass graft surgery (CABG) and PTCA has been published recently in The New England Journal of Medicine. The relative expense is highly dependent upon the rate at which the narrowing returns. If means can be found to decrease the rate of restenosis (continued narrowing of the artery) in PTCA patients, and if the technique can be successfully applied to patients with multivessel disease, substantial savings will accrue.

Question: This technique was developed using NIH support, wasn't it?

Answer: No, it was not. Dr. Andreas Gruentgit of Sweden, after many years of balloon dilation experience in peripheral vascular disease, first applied the technique of angioplasty to a narrowed coronary artery in September 1977. As the technique became more widely used, the NHLBI established a voluntary patient registry to develop estimates quickly about efficacy and risk. The registry gathered and published data, quickly identifying a learning curve (pattern of improved skills with increased experience) for physicians starting to do PTCA, as well as documenting acute and chronic outcome with experienced operators. In addition, NHLBI is supporting a study at the Mayo Clinic designed to identify means of reducing the rate of continued narrowing of the artery. Our intramural research program is also evaluating this technique.

Question: How will your reduction in the FY 1986 budget affect this research?

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Answer: We expect research in this area to continue at an acceptable level. The two pressing problems in PTCA which require prompt resolution include the prevention of restenosis in successfully dilated arteries, and the determination of whether PTCA can be successfully and generally applied to patients with multivessel disease.

More basic research will be required to understand the mechanism of restenosis. Now that PTCA is beginning to be used more often as a mode of therapy, NHLBI is initiating a multicenter trial designed to compare PTCA with CABG in patients with multivessel coronary disease and serious symptoms.

COST OF GRANTS

Question: You are projecting the average cost of a research grant at about $200,000 in FY 1986, up from $187,000 in FY 1985. This is about a 7% increase. In the light of the fact that the nation's rate of inflation is about 4%, how do you project a 7% rise in cost of doing research?

Answer: The increase in the average cost of research project grants for the NHLBI is approximately 10 percent per year when considered over the 5-year period from 1981 through 1986. This increase in average costs is due to inflation and the application of increasingly sophisticated technology to biomedical research problems. The NHLBI believes a 7 percent inflation factor in 1986 is a reasonable estimate based on our historical trends. In fact, a portion of the data on which this estimate is based is already available from 1984 awards, and shows an increase in average cost from 1985 to 1986 greater than 7 percent. However, these data comprise only a part of the total estimate.

Question: I understand that last year your cost estimates were somewhat overestimated. Is that correct? Please explain how this came about and how the unobligated funds were used?

Answer: The NHLBI based the cost of funding research project grants in 1984 on historical trends. Our estimated average cost was higher than the actual average turned out to be. The difference between these estimates and the end of year actual was due largely to a decline in the average cost of competing research grants in one of our programs. This was a significant departure from recent experience and we do not think it will happen again.

We responded to this change by attempting to minimize its impact on the historical balance among the heart, lung, and blood program areas. We paid more grants to a higher payline in the heart program, took advantage of new scientific opportunities in the ischemic heart disease SCOR program, and expanded demonstration and education research, a high priority area for the Institute. Furthermore, we were able to respond to rapidly expanding AIDS research requirements.

RESEARCH PRIORITIES

Question: The NHLBI has responsibility for research in several inter-related but different areas. What mechanisms are used to establish the Institute's research priorities?

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Answer: Research priorities for each year are developed through the NHLBI planning process which involves a series of interactions among the NHLBI program staff, the Institute's scientific advisory committees, and the scientific community.

Through mechanisms such as workshops and conferences, and through reviews of scientific literature, the Institute receives advice and recommendations on research needs from the scientific community at large and from the NHLBI advisory committees. Based upon these recommendations, NHLBI staff develop promising areas of research into specific initiatives that are then reviewed, approved, and ranked in order of priority by appropriate NHLBI advisory committees. I review these initiatives with the Institute staff for program relevance and priority, and present them for final review and approval to the National Heart, Lung, and Blood Advisory Council.

Question: Do these priorities remain constant from year to year?

Answer: The overriding priority of the National Heart, Lung, and Blood Institute is to conduct a properly balanced, high quality research program to combat diseases of the heart, lungs, blood vessel, and blood. The nature of our studies and the research approach we use, however, change year to year as scientific opportunity and needs change. As I described earlier, our planning process permits us to maintain a sensitive communication with the scientific community. We respond to their recommendations and, within the framework of our mission, adapt our approach and priorities for research to take advantage of new knowledge and to respond to public health issues.

Question: As Director, how much discretion do you have to shift funds as new research areas are identified or as emergencies such as AIDS occur from time to time?

Answer: The NHLBI planning process and our efforts to assess and take advantage of the state-of-the-science through the advice of our scientific community help us anticipate and thereby respond to emerging research areas within the annual cycle of review and funding. To meet emergencies, such as AIDS, we can use the contract mechanism to address pressing research questions or the program announcement to stimulate grant applications. The state-of-the-science and balance among programs, however, are factors to be considered with regard to shifting funds.

PREVENTIVE RESEARCH

Question: What types of preventive research are being done by your Institute?

Answer: Our research spectrum includes basic research, applied research, clinical trials, and demonstration and education research. Prevention related research can be found at each step of this spectrum. For example, today we are preventing diseases that result from hypertension with an impressive array of drugs that was not in existence 15 years ago. These drugs were developed as we gained a better understanding of the complexities of the patho-

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physiology of high blood pressure. That understanding was provided through basic research which will also provide us with the ultimate prevention tool when we find out precisely what causes hypertension. Our clinical trials research often provides the basis for significant changes in medical practice or public health actions. For example, the Coronary Primary Prevention Trial (CPPT) was a clinical trial which provided us with major new evidence linking the reduction of elevated cholesterol levels with the reduction of coronary heart disease incidence. The evidence from that major study and related research are serving as the basis for our new National Cholesterol Education Program. In the area of demonstration and education, we recently took the lessons learned from three studies on preventing or controlling attacks among asthmatic children and gave them wide dissemination. These research studies showed that intervention can prevent some asthma attacks, reduce the severity of other attacks when they occur, reduce the demand for medical services, and lower related medical costs. There are many more projects we could cite to illustrate how varied and far-reaching our prevention research activities are.

Question: What percent of your budget is directed to preventive research?

Answer: In responding to that question, I feel compelled to point out that we may be somewhat conservative in how we identify that which is described as prevention-related research in the Institute. As I indicated earlier, with all the progress in reducing the level of hypertensive-related diseases, the ultimate prevention will come from understanding the causes of hypertension. We don't know them now. Most of the research which may lead to this understanding is in the area of basic research and is not listed as prevention research. That which is technically classified as "prevention" represented better than 450 research projects totalling more than $137 million in 1984, or about 20 percent of our overall research program.

Question: How are the results of this research being translated into useful public information?

Answer: We have a very ambitious information/education program aimed not just at the public but at all health professionals who deal with the public. We employ mass media, such as radio and television public service messages, billboard and transit card advertising, print ads in newspapers and magazines, and the placement of articles in a range of print media. Through these channels we carry Institute messages directly to the public. Equally important, if not more important, are the educational networks we form with many organizations and groups. Often these are medical, nursing, and public health organizations such as the American Medical Association, the American Public Health Association, and the American Nursing Association, all of which are represented on the Coordinating Committee of our National High Blood Pressure Education Program. We work with insurance companies in developing pilot health promotion and disease prevention programs for their group subscribers, and assist them in putting disease prevention incentives in their policies. We are convinced that the Federal Government cannot and should not carry out major national education efforts on its own. It must develop a far reaching partnership

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with others in various segments of our society if we are to have the maximum impact. We feel strongly that by serving as a coordinator and catalyst for these efforts we can educate the public much more effectively than trying to do the whole job by ourselves from Washington. Our major effort in this area thus far has been in the implementation of the National High Blood Pressure Education Program. Two other programs are being developed. One is the National Cholesterol Education Program and the other is the NHLBI Smoking Education Program.

CREATIVE RESEARCH

Question: I understand that you have made limited use of the Director's decision to fund innovative or creative research proposals that have not received high priority scores. To what extent is research being funded on the basis of success predictability criteria rather than funding new or innovative research?

Answer: The NHLBI funds research primarily on the basis of scientific merit, which includes considerations of success predictability, importance, and innovation. Innovative approaches to research problems are perhaps the major elements that the peer review system considers in assigning priority scores to applications being reviewed. It has been our experience that the grant applications which have been judged to be the most meritorious are those which reviewers feel are new and innovative, address important biomedical problems, and are the most likely to provide the needed information.

Question: To what extent do you as Director excercise flexibility in awarding grants outside the priority ranking of the peer review system?

Answer: Our policy has been to rely primarily on the recommendations of the peer review process for advice on the funding of grants. However, on a continuing basis, staff of the Institute and members of the National Heart, Lung, and Blood Advisory Council (NHLBAC) review and recommend for support a number of applications which may be outside the priority ranking of the peer review system. These recommendations are made for many reasons including new and innovative research, program balance, timeliness of the research (e.g., Acquired Immunodeficiency Syndrome - AIDS), and so on. Although the percentage of grants funded by the NHLBI on this basis is relatively low, its impact can be significant and represents the considered collective scientific wisdom of Institute staff and membership of the NHLBAC.

Question: What is your feeling about this discretionary ability?

Answer: In my view, discretionary authority for awarding grants is an essential tool for the management of biomedical research. It provides the flexibility to meet the needs of program balance and at the same time to ensure that research of the highest scientific merit is supported.

Question: Should Congress earmark funds specifically for innovative research?

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Answer: I believe that Congress should not earmark funds specifically for innovative research. As indicated above, a major element considered in the determination of scientific merit is the issue of innovation; as such, innovative research is currently being supported by this Institute. In addition, NHLBI staff and members of the National Heart, Lung, and Blood Advisory Council identify and make recommendations on new and innovative research grant applications. Finally, the NHLBI is discussing a small grant program to provide 2 years of research support. One of the purposes of this grant mechanism would be to support feasibility studies of innovative and high risk research which would provide a basis for more extensive research if the ideas show potential. Similar small grant programs have proven to be successful in the National Institute of Dental Research and the National Eye Institute.

RESEARCH COORDINATION

Question: I understand that over the years biomedical research has become more basic and the lines between the Institutes have become blurred. How does your Institute coordinate with other Institutes doing similar research?

Answer: The central referral process for applications at NIH, performed in the Division of Research Grants, precludes wasteful duplication of research efforts by the various funding units. Often an application may be assigned to two or more Institutes. Thus, a decision may be reached to share in the funding of certain applications, or more often one Institute will agree to act as the sole funding source. In the case of solicited research programs in which investigators are invited to prepare research in specified, underserved research areas, discussions are held with all other Institutes that properly have a programmatic interest in the area identified. Each has a knowledge of the solicitations before they are announced and may participate in funding or in oversight of the results of research eventually supported by the originating Institute.

Question: How does your Institute coordinate with other agencies outside of NIH doing similar research?

Answer: Coordination and sharing of research progress with other agencies is accomplished primarily through several Interagency Technical Committees, whose memberships are composed of senior scientists from the involved agencies. Currently, these are the Working Group on Blood and Its Substitutes; Working Group on Cardiovascular Biomedical Engineering; Working Group on Nutrient Composition of Foods; Working Group on Health Status and the Cost and Benefits of Health Research; and Working Group on Smoking and Heart, Lung, and Blood Diseases. We believe these groups are an effective means for coordination of multiagency concerns. In addition, scientist representatives of other Federal agencies often serve as ex officio (voting) members of our peer review groups and our Advisory Council. For example, the Department of Defense, the Veteran's Administration, and the Office of Science and Technology Policy have membership on the Advisory Council; a senior staff member of the National Science Foundation serves in a liaison capacity.

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Question: Describe the coordination between the intra and extramural programs.

Answer: The intramural and extramural programs of the NHLBI both support research in the basic sciences as the foundation of modern medical practice. Not suprisingly, therefore, there are areas of investigation common to each, and full advantage is taken of this unique opportunity that is provided for the cross-fertilization of ideas. A recent innovation at the NHLBI has been the establishment of a series of conferences, "Frontiers in Science", in which intramural scientists and those receiving extramural support address new developments in biomedical research relating to diseases of the heart, lungs and blood. These conferences are attended by extramural program staff, review staff, intramural investigators, senior management and leading scientists from the academic community. Such interrelationships can, and do, result in new research initiatives. For example, a recent "Frontiers" presentation by a senior intramural investigator, on the molecular basis of muscular contractility, led directly to the issuance of a solicitation for complimentary research in this area by the extramural Heart Program. In a similar way, a strong working relationship has been developed between the extramural Lung Program and the intramural Pulmonary Branch over the utilization of gene splicing in work on an inherited form of emphysema. The extramural Blood Program, utilizing an intra-agency funding agreement, is providing financial support and access to the NHLBI non-human primate colony for intramural scientists from the NIH Clinical Center who are developing an animal model for the transmission of the AIDS agent by blood. Although the conventional lines drawn between the institutes provide for suitable and necessary ways of assigning authority and responsibility, they do not interfere with the support of the best and most appropriate research into the pressing problems of heart, lung and blood diseases, and the safety of the nation's blood supply.

LONG-RANGE FUNDING PLANS

Question: We are told that research is expanding at a rapid rate with new opportunities appearing all the time. What attempts are made to look five or ten years ahead in terms of funding needs?

Answer: The NHLBI makes every effort to be sensitive to new research opportunities through its formal planning process and through communication with the lay and scientific community. We are responsible for a National Program of research on diseases of the heart, blood vessels, lung, and blood. On an annual basis I prepare a report for the President, for transmittal to the Congress, on accomplishments of the National Program during the preceding year and on plans and projected resource needs for the coming 5 years.

This 5-year projection is reviewed and revised annually on the basis of an evaluation of progress and accomplishments and on assessment of scientific need and opportunity.

Just recently, we completed an extensive, in-depth review of our goals, objectives, and achievements over the past 10 years. The results of this review, and new and revised goals and objectives for the next 5 years, are reported in the "Ten-Year Review" and "Five-Year Plan" of the National Heart, Blood Vessel, Lung, Blood Diseases, and Blood Resources Program.

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In addition, the Institute provides for forward planning through its biennial implementation plan which is the final step in a year-long process of planning and evaluation. The Plan's purpose is to present proposed new initiatives with reference to scientific opportunity and need, program relevance, and needed resources.

Each of the Institute's programs prepares a biennial implementation plan. The plans reflect decisions reached by the Institute's scientific advisory committees and NHLBI staff on future directions for research.

Each plan is analyzed and reviewed by me and discussed with the program administrators. Together, we reach agreement on priorities, initiatives to be pursued or deferred, and the funding levels. These agreements constitute the Institute's Program Plan for the coming 2 fiscal years which we present to our National Advisory Council for review and approval.

Question: Research priorities?

Answer: The NHLBI seeks to maintain a balanced program of research activities building upon basic research and proceeding through the necessary and interrelated steps of clinical application, validation, and education.

A continuing priority in the realization of a balanced program is support of investigator initiated research. We also view our centers mechanism as an effective means of concentrating resources, facilities, and manpower on selected high priority topics in heart, lung, and blood diseases. We believe that the multidisciplinary nature of the centers program provides a valuable complement to the Institute's portfolio of investigator-initiated research projects.

We also use our planning process to help identify areas that are ready for research exploration. Each year, our research programs staff are asked to identify new and emerging areas of scientific opportunity. These areas are selected because they have high priority, are prospective, and are feasible if resources are available. The areas form the basis of the NHLBI Forward Plan, reviewed annually with the Director, NIH, and the framework for development of specific research initiatives in our Biennial Implementation Plan.

Question: Training needs?

Answer: Projections for research training needs are also made with reference to an assessment of emerging scientific opportunities. As part of my Annual Report, which I mentioned earlier, the Institute presents resource needs for the coming 5 years for trained biomedical researchers. These projections are in areas ready for scientific exploration but in need of trained personnel to exploit every opportunity. In recent years, the Institute has put considerable effort into encouraging and supporting researchers in the rapidly expanding fields of biochemistry, biotechnology, cellular and molecular biology, and genetics.

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To respond to changing training needs, the Institute carefully monitors its programs, evaluates their effectiveness, and assesses emerging needs in the research community. As existing training programs reach their objectives, they are either adjusted to fit new requirements, or they are replaced by new programs. The National Pulmonary Faculty Training Program was initiated to increase the number of well-trained biomedical teachers in the pulmonary field and to provide role models for aspiring students with the ultimate goal of increasing the number of pulmonary researchers. Subsequent analysis showed that most of the objectives of this program had been reached and that the need for pulmonary specialists in most subspecialties would be met in the late 1980's. Therefore, the program was phased out.

CHANGE IN LENGTH OF GRANTS

Question: Do you favor the 5-year grant period over the currently used 3-year period?

Answer: The 3-year grant period is an average length of support and is not a limitation as a matter of policy. In fact, the NHLBI currently supports grants for 4 and 5 year periods. However, a significant number of grant applications that request 5 years of support have been recommended by Initial Review Groups (IRG) for 3 years of support. In those cases where the reduction in the length of the recommended support cannot be justified by the IRG, the Institute, with the recommendation of its Council, is restoring the grant period to 5 years. We believe that this effort will provide some measure of stability to the biomedical research community and at the same time will reduce the administrative burden on the Federal government and applicant institutions resulting from more frequent reapplication.

Question: How should a new investigator be treated if the current policy is changed?

Answer: The current policy for traditional research grants is to provide up to 5 years of support. We believe this policy is reasonable. Some investigators apply for less than 3 years of support if they feel the research can be completed in a shorter time. As far as the new investigator is concerned, we are proposing to increase the length of the New Investigator Research Award from up to 3 years to up to 5 years in order to provide encouragement and stability to investigators at the beginning of their careers and to ensure a supply of able biomedical researchers for the future.

Question: Will a 5-year period change funding requirements for your Institute?

Answer: Again, it should be pointed out that there is no policy to preclude 5-year funding periods in our regular research grant program. Every applicant is free to request 5 years of funding if he or she feels the research proposed will require that length of time. In general, the reasons for recommendations for grant awards that are shorter than 5 years are two-fold. As mentioned earlier, some investigators request shorter durations. In some other cases, Initial Review Group reviewers believe the

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research can be completed in less than 5 years. Occasionally, the nature of the proposed research is considered preliminary with few or no pilot data to suggest feasibility; in these cases, if the research proposed is considered particularly innovative, reviewers will often recommend shorter durations of support in order to give investigators the opportunity to demonstrate that feasibility.

We believe, in this way, accountability for the expenditure of research funds is optimized. Thus, the effect of longer duration of awards would have only a minimal effect on our funding requirements. The major effect would be on administrative costs applicable to the processing and review of more frequent applications if those investigators received shorter awards.

Question: What will be the effect upon administrative costs if your Institute shifts to a 5-year grant period?

Answer: Since the NHLBI has already moved to restore the length of grant support when justified, we would anticipate that administrative costs to the Institute and NIH generally would be reduced in proportion to the reduction in frequency of applications from investigators. In addition, applicant institutional savings resulting from less frequent competitive application submission will also occur.

Question: How does the research scientist feel about a 5-year grant?

Answer: In general, the scientific community favors longer grant periods when justified by the proposed research. The longer grant period would promote more research by reducing the time involved in grant application preparation. In addition, the longer grant period would provide increased stability for the research endeavor, and this stability would encourage more innovative approaches to disease problems.

CONSTRUCTION

Question: Last year this committee provided your Institute with funds for construction and rehabilitation. How were these funds used?

Answer: The NHLBI announced a grant program to support the improvement, renovation, and establishment of modern research facilities relevant to contemporary biomedical sciences (e.g., molecular biology) in organizations with substantial, ongoing research activities in heart, lung, and blood diseases. Grants awarded under this program are used for the purpose of renovating or establishing physical facilities, primarily laboratories, to provide groups of NHLBI-sponsored investigators with access to contemporary, complex, or expensive techniques and methods that will broaden or improve their research. These modern research facilities are to serve several research projects on a shared basis. The funds awarded may be used to repair, renovate, rehabilitate, modernize, remodel, and improve physical facilities so as to expand research activities and to introduce modern investigative techniques. The new or expanded physical resources to be established must be for research purposes. Examples include shared basic research labora-

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tories, combined or integrated laboratories, and core resources (e.g., tissue or cell culture laboratories, cell biology and biochemical genetics laboratories, imaging facilities, or immunogenetic laboratories).

The Institute has attemped to maximize the benefits of the appropriation by requiring commitments for matching funds from non-Federal sources to be included in the applications. Even with awards limited to $500 thousand and applications restricted to institutions with over $5 million in NIH research support in heart, lung, and blood activities, the NHLBI received letters of intent from 21 of the 36 eligible institutions. The 1985 current estimate should permit the Institute to make between 6 and 8 awards.

Question: My discussion with Dr. Wyngaarden indicated a vast need for rehabilitating the extramural physical plant. How many dollars would you estimate your Institute would require each year over the next decade to meet these needs?

Answer: With 36 institutions eligible for awards under our present criteria and between 6 and 8 awards to be made in 1985, there will remain after this year a large demand for renovation support in 1986 and beyond. Given the length of time that has elasped since the last construction authorization, it is also likely that there is an additional widespread need for construction support to provide new and modern research facilities for heart, lung, and the blood research.

The Institute anticipates that funding of $30 to $40 million over the next decade would meet many of this Nation's more critical needs for updating heart, lung and blood research facilities. This estimate assumes that $4 to $5 million will be made available each year for the next 3 to 5 years, which will lead to a reduced need of approximately $3 million per year beginning in the early 1990's.

AIDS

Question: Dr. Lenfant, in your opening remarks you spoke about blood transfusion and AIDS. Can you give us an update on AIDS cases in this country and tell me what kind of research programs you are supporting to reduce or eliminate transfusion-associated AIDS?

Answer: As of March 4, 1985, the Centers for Disease Control reported 8,697 cases of AIDS in the United States of which 4,179 have died. Public health experts estimate that approximately 400,000 Americans may have been exposed to human T-cell lymphotropic virus, type III (HTLV-III) which appears to be the causative agent of AIDS. The virus is transmitted through sexual contact, by the use of contaminated needles that have been shared, and through blood and blood products. In the United States bloodrelated cases of AIDS account for approximately 2 percent of total cases, which include 104 transfusion-associated cases and 68 cases in hemophiliacs.

In response to this serious epidemic the NHLBI is supporting a number of projects. The NHLBI has completed a 200,000 serum samples collection from randomly selected blood donors for the identifica-

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tion of the prevalence of antibodies to HTLV-III in normal donors. This serum repository will be used for testing antibodies to HTLV-III, identification of seropositive donors and recipients of blood products from these donors, follow-up of the recipients, and data analysis.

Another project is having success in developing and validating an animal model for future testing of vaccines, therapeutic agents, and safety of biological materials from high-risk donors.

The NHLBI is planning to implement two important projects concerned with the prevention of AIDS in hemophiliacs and other groups exposed to AIDS. One project will support research on the development of methods to inactivate HTLV-III in blood derivatives, particularly in factor VIII concentrates. Studies will include physical, chemical or immunological approaches to inactivation that preserve the physiological integrity of the blood derivative. The second project will encourage the development and production of an investigational immune globulin that may be useful for post-exposure prophylaxis of AIDS.

Finally, one of our initiatives is aimed at the development of second-generation screening assays for the detection of HTLV-III antibody or antigen. Antigen detection assays may be more effective in the identification of the HTLV-III carrier state because recent findings have demonstrated that a carrier state may exist in the absence of detectable antibodies to the virus.

Question: Was the recently announced AIDS blood test developed with NIH support?

Answer: The enzyme-linked immunosorbent assay (ELISA) recently licensed to screen blood and plasma donations for HTLV-III antibody was originally developed at the NIH. The commercial ELISA kits were developed under non-exclusive, royalty-bearing licenses from the Department of Health and Human Services. These tests are modifications of the ELISA as described by NIH scientists in the spring of 1984.

Present U.S. Public Health Service recommendations suggest that all blood or plasma should be tested for HTLV-III antibody by ELISA, and that any unit found to be positive on initial testing must not be transfused or manufactured into other products capable of transmitting infectious agents.

Question: Do you think that the money was well spent?

Answer. Undoubtedly, the dollars invested in the development of the ELISA for detecting HTLV-III antibody will prove to be money well spent. This screening test now provides us with the capability of limiting transmission of HTLV-III in some groups. For example, blood transfusion-associated cases of AIDS should decline, although the effect on incidence may take several years to become apparent due to the prolonged incubation period of the disease. Similarly, AIDS in hemophiliacs should decline with HTLV-III screening of the plasma employed to prepare factor VIII concentrates as well as the use of heat treated factor VIII preparations.

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Question: We know of your prospective study on AIDS and heard of the difficulities you had in developing the informed consent used in the study. Has this resulted in a cost increase?

Answer: The informed consent provisions of this study will require unforeseen expenditures. One provision of the informed consent document was that all donors whose blood is tested and who are found to have antibody in their blood will be so advised and will be offered additional tests. The current plans are that these donors would be offered an additional ELISA test (the type of screening test which is being initiated in most blood banks) and a confirmatory test, probably the Western blot test. The exact cost for these procedures will depend upon the number of donors who are positive. However, we do know that the cost will be about $100 per person.

In addition, the cost for purchase of test kits for this study could not be estimated at the time the study started. This cost is significant for the number of specimens in the serum collection and for the subjects in the study.

Altogether, the cost for test kits and for confirmatory Western blot tests could be as much as $4.3 million, of which $1.4 million is needed in 1985 and $1.9 million in 1986.

Question: If so, have you been obliged to shift funds from other programs?

Answer: In order to provide support for this activity, funds will need to be shifted from other programs.

OCCUPATIONAL LUNG DISORDERS

Question: Last year the Committee directed you to expand your research on respiratory diseases caused by occupational exposure. How did you respond to this in FY 1985, and what are your plans for FY 1986?

Answer: The Lung Program of the Institute has provided support for occupational lung diseases through its Specialized Centers of Research Program for many years. Research on diseases such as Farmers Lung, silicosis, asbestosis, byssinosis and occupational asthma has been fostered through the Institute's centers program.

In 1985 the Lung Program announced a competition for new and renewal applications for Specialized Centers of Research in the Occupational and Immunologic Lung Disease category. To date there appears to be much interest in this announcement and it is expected that a number of applicants will gain support for five years starting in 1987. In addition, the Institute plans to hold a workshop in 1985 on "Strategies for Elucidating the Relationship Between Occupation and Chronic Airflow Disease" and a second workshop in 1986 on "Assessment of Impairment in Interstitial Lung Diseases." Both of these workshops are expected to provide a summary of the current knowledge on these topics and future needs for research in occupational pulmonary diseases.

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RESPIRATORY DISTRESS SYNDROME

Question: Prematurely born babies often develop what is known as respiratory distress syndrome. Does the Institute have a research program addressed to this disease?

Answer: Research into improved detection, management, and prevention of neonatal respiratory distress syndrome (also know as hyaline membrane disease), is a major component of the Institute's program in pediatric pulmonary diseases. The Institute is currently supporting six Specialized Centers of Research which combine basic research projects on neonatal lung biology with clinical studies of respiratory distress syndrome.

Question: If so, what are the accomplishments?

Answer: During the last ten years advances in obstetrical and newborn management, particularly improvements in ventilatory therapy and support of metabolic needs of the newborn infant, have resulted in a dramatic reduction in mortality from this syndrome, the rate falling from the range of 70 percent to as low as 10 percent in some centers. Many accomplishments can be cited from the National Heart, Lung, and Blood research program in neonatal lung disease that have contributed to this reduction in mortality.

Investigators have developed improved methods for detecting infants at high risk of developing respiratory distress syndrome using a simple foam test of amniotic fluid and analysis of high-risk pregnancies such as maternal diabetes and delivery by cesarean section. Significant achievements have also been made in our knowledge of basic biology of the developing lung and of lung surfactant, a lipidprotein complex that is essential for normal breathing but that is deficient in premature infants with respiratory distress syndrome. This basic research has led to the development of synthetic and natural (i.e. from cow lung) surfactant preparations that are now being tested to see if replacement therapy will be useful in alleviating, or even preventing, lung disease in these premature infants. Molecular biological approaches to clone the gene for surfactant protein now underway may eventually lead to new strategies for surfactant replacement. Investigations into how hormones such as steroids, thyroid hormones, insulin, and labor-delaying drugs may enhance lung maturation and, hence, the incidence of respiratory distress syndrome, have also been undertaken. An Institute-supported multicenter clinical trial to evaluate antenatal steroid therapy in in preventing respiratory distress syndrome was recently completed. The study showed that steroids given to the mother 24-48 hours before delivery does reduce the incidence of lung disease, but that the effect seems to depend on multiple factors, including the sex and race of the infant. An unexpected finding was that the steroid (dexamethasone) was highly effective in preventing the occurrence of a serious disorder in newborns (necrotizing enterocolitis). Studies indicate no adverse effects of steroid treatment on intellectual and neurologic development of infants for up to three years of life.

Studies of the pathophysiology and treatment of respiratory distress syndrome in subhuman primates have added new understandings about the adverse effects of the high ventilatory pressures

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and oxygen concentrations that must sometimes be used to treat serious cases of lung disease in premature infants. One method currently under investigation is the use of high frequency ventilation, a mode of ventilation that may provide oxygen to the patient without using high airway pressures. Extensive studies in animals are currently ongoing to delineate the safety measures and standardize the conditions that must be met when applying high frequency ventilation to premature infants with breathing problems. The Institute is supporting a multicenter clinical trial to determine the efficacy of high frequency ventilation as compared to conventional mechanical ventilation in the management of infants with neonatal lung disease.

MINIATURE HEART-LUNG MACHINE

Question: What is the potential impact of the miniature heart-lung machine that is now being used in some neonatal intensive care units?

Answer: A miniature heart-lung machine has recently been introduced into some neonatal intensive care units, including Children's Hospital in Washington, D.C. The machine takes over lung function for babies with serious respiratory problems, adding oxygen to the blood, removing carbon dioxide, and allows the infant's lungs to heal and mature properly. It is currently being used to treat infants born with meconium aspiration which is caused by the baby's feces contaminating their lungs before birth. Babies with persistent circulation problems, where their underdeveloped lungs cannot accept their blood flow, and diaphramatic hernias, where the bowel presses into the chest cavity and prevents the lung from functioning properly are also candidates for this machine.

One problem with the use of this machine is that it requires the use of medication in babies to prevent blood clotting (anticoagulants). This significantly increases the risk of hemorrhage. It is therefore unlikely that this technique will be of much help to infants of very low birth weight who are already prone to cerebral hemorrhage. Other possible complications are a high risk of infection and problems arising from the surgical procedure. Nonetheless, the preliminary results are promising enough to warrant further evaluation, since the technique appears to have a beneficial role to play in particular instances as mentioned above.

BROWN LUNG DISEASE

Question: Doctor, there is a large textile industry in America and there has been considerable publicity in recent months about Brown Lung Disease. What is this disease, and what relation does it have to textile manufacture?

Answer: Brown lung disease is a popular lay term for byssinosis, an occupational lung disease occurring primarily in the cotton textile industry, but also afflicting workers in the flax or hemp industries. Initial symptoms are characteristic of an acute reaction of the lungs to cotton dust, and occur only on the first day back to work following a holiday or weekend, hence another laymen's term, "Monday fever." The early symptoms include tightness in the chest, wheezing, cough and low grade fever. These symptoms

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usually last for only a day, but as exposure continues they extend throughout the working week. In the presence of continued exposure workers can become respiratory "cripples" with chronic bronchitis and emphysema, painful and difficult breathing, and persistent and productive cough. At this stage the worker cannot find relief even in the absence of exposure. Some individuals develop byssinosis soon after starting work while others become symptomatic only after many years on the job. Many cotton textile workers suffer only mild symptoms which never worsen over many years; in others the disease worsens within a few years. The most effective current strategy is to use dust control measures to significantly reduce the incidence of disease.

Question: Is any research on this problem being done by the National Heart, Lung and Blood Institute?

Answer: The NHLBI is providing support for a five-year study involving about six thousand textile workers in nine plants. The goal of this study is to determine and quantitate the risk for development of chronic obstructive airways disease which may occur as a consequence of cotton dust exposure in textile manufacturing. Emphasis is being placed on the "low end" of the dose-response relationship since employment of dust control measures appears to be effective in reducing exposure levels of workers in the industry, and thereby reducing the most severe forms of the disease.

ASBESTOS

Question: During the past year there have been a number of articles describing concern about exposure of people to asbestos in public buildings such as airports, schools, and government offices. Is there a real threat from these types of exposures and what is the NHLBI doing about asbestos-related diseases?

Answer: Exposure to asbestos, even in relatively small amounts, has been associated with an increased incidence of cancer, principally mesothelioma, and asbestosis, an irreversible fibrous scarring of the lungs. Although the malignant neoplasms associated with exposure to asbestos have a higher mortality, asbestosis is the most common asbestos-related disease. The long latency of asbestos-related disease makes investigation very difficult, as individuals may not become symptomatic for 20 to 30 years after their exposure. Thus, there is concern that a great deal of asbestos-related disease from exposure to asbestos in public buildings may eventually be seen. As of now, there is no truly effective treatment for any of the asbestos-related diseases; prevention through control of exposure is currently the only effective approach to dealing with these diseases.

The NHLBI is currently supporting a number of research projects to examine basic mechanisms which lead to the development of fibrosis by asbestos fibers. The cause of the chronic form of asbestosis leading to debilitating or even fatal disease is not yet known. However, it is known that asbestosis patients have altered immune responses. Thus NHLBI-supported researchers are working to determine if altered immunologic function plays a role in pathogenesis of asbestosis. Studies are also being carried out on interaction of asbestos fibers with various cells present in the lung.

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As the mechanism of the disease process is better understood, methods of early detection and effective treatment for asbestosis patients may eventually become available.

MINORITY RESEARCH

Question: The NHLBI has been supportive of programs that develop minority individual and institutional research capabilities. Please describe your recent approaches and accomplishments in this area.

Answer: To facilitate our continued effort to develop minority individual and institutional research capabilities, the Institute has developed several initiatives that formed the NHLBI Minority Investigators and Minority Institutional Research Plan. A significant event which led to the development of this plan was a "Task Force" formed by the NHLBI executive staff together with representatives of the Association of Minority Health Professions Schools. Phase I of this plan consists of 4 initiatives that have been widely announced to the minority community and have a common application receipt date of April 1, 1985. The initiatives are:

1) Minority School Faculty Development Award is designed to encourage the development of faculty investigators at minority schools in areas relevant to cardiovascular, pulmonary, and blood disease research. Each candidate is to identify a mentor at a nearby institution (approximately 100 miles) who is recognized as an accomplished investigator and who will provide guidance for the awardee's development and research plan. Each award will have a duration of 5 years.

2) Minority Institutional Research Training Program is designed to train graduate students from minority schools and to expose them to a sophisticated program in cardiovascular, pulmonary, or blood research. It will also serve to stimulate fundamental research and prevention and control studies by offering minority school graduate students the opportunity to enhance their research capabilities.

3) Research Fellow Program for Investigators at Minority Institutions is designed to provide opportunities for investigators at minority institutions to acquire experience in the use of sophisticated biomedical technologies and laboratory techniques available for heart, lung, and blood disease research at the NIH. The research fellow from minority institutions will receive one year of extensive research training in one of the laboratories of the National Heart, Lung, and Blood Institute.

4) NHLBI Visiting Professor Program is designed to assist in the development of the institution's capability for research; to attract more of their students into biomedical research careers and to increase their participation in the biomedical research enterprise. Under this matching program, intramural research scientists and extramural health scientist administrators of the NHLBI staff would spend limited periods of time assigned to minority institutions. The NHLBI will continue to pay the salary of the visiting scientist. The institution will provide housing and subsistence during the assignment and, if possible, provide cost of travel.

A predecessor to these four initiatives was the Minority Hypertension Research Development Summer Program, which has been very

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successful and instrumental in recruiting and developing minority faculty members and graduate students for research careers in hypertension. This pilot program will be phased out by 1989. In 1984, the Division of Lung Diseases initiated a similar Minority Summer Program of Pulmonary Research designed to provide opportunities for minority school faculty members and graduate students to gain experience and exposure to ongoing pulmonary research projects in established pulmonary training centers.

The NHLBI/Association of Minority Health Professions Schools Task Force will review periodically the status of each program to determine the effectiveness in fulfilling its objectives. In addition, the Task Force is discussing possible initiatives for Phase II of the Research Plan.

CORONARY HEART DISEASE IN BLACK AMERICA

Question: The NHLBI has been on the forefront of developing programs for minority investigators. Are any new programs being developed regarding coronary heart disease in Black America?

Answer: A new program for which a request for proposals was issued in October, 1984 and responses are currently being reviewed is entitled, "Development of Obesity in Young Black and White Females: Longitudinal Studies of Cardiovascular Disease Risk Factors." The goal of this program is to determine whether the black-white difference in the development of obesity in females during adolescence is due to psychosocial, socioeconomic and other environmental and/or biologic factors, and whether these differences in the development of obesity are associated with the occurrence of other heart disease risk factors such as hypertension, and elevated low density lipoprotein cholesterol.

The Community and Cohort Surveillance Program (CCSP), scheduled to begin in September 1985, is planning to follow samples of 4000 adults for the development of coronary heart disease and stroke in each of four U.S. communities. NHLBI intends to fund one of these centers to study a sample whose participants are 90% or more black. Contracts will be let for 8 years and during this time, each participant will have two detailed examinations.

The longitudinal study of Coronary Heart Disease Risk Factors in Young Adults (CARDIA) is designed so that 50% of the participants will be black; equally divided by sex. Special attention has been accorded to recruitment of the black populations in the four study areas to ensure adequate representation by age and socioeconomic status.

EMPHYSEMA AND COPD

Question: We understand that emphysema and chronic obstructive lung disease may result from a relative excess of enzyme which destroys lung tissue. What research is being done?

Answer: The current concept of pathogenesis of emphysema is generally referred to as the "protease-antiprotease imbalance hypothesis." This hypothesis resulted from research on a rare genetic defect resulting in deficiency of alpha-1-antitrypsin which checks the activity of tissue digesting enzymes (proteases) in the

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lung. It is believed that this deficiency leads to a high incidence of emphysema in individuals with this defect, especially if they smoke. Current research is focused on understanding the mechanisms underlying the development of emphysema in those with and without the genetic defect.

Question: Are there some good prospects to find a treatment for these conditions?

It has been shown that cigarette smoke plays an important role in induction of the disease, as investigators have found that cigarette smoke inactivates alpha-1-antitrypsin. Cigarette smoke also has been shown to stimulate the migration of inflammatory cells which release proteolytic enzymes into the lungs. These two conditions result in excess proteolytic activity in the lung causing dissolution of lung tissue. To investigate these processes scientists have developed several animal models. New tools of biotechnology are also being put to use to understand this disease process; scientists have cloned the normal and defective genes for the protease inhibitor and are studying its expression. Development of an animal model for the antiprotease deficiency, using techniques in genetic engineering, may provide a useful model for unraveling the pathogenetic processes in emphysema and to evaluate drugs against this disease.

Question: Are there some good prospects to find a treatment for these conditions?

Answer: At present, emphysema is a terminal disease for which there is no treatment. However, through support from the National Heart, Lung, and Blood Institute, scientists are actively pursuing potential new directions to develop possible modes of therapy. Since emphysema is thought to be caused by an imbalance between proteolytic enzymes that destroy tissues (proteases) and alpha-1-antitrypsin, (an antiprotease) new research efforts related to treatment of emphysema are based on restoring this balance. For example, replacement of normal human alpha-1-antitrypsin in the genetically deficient individuals is one suggested approach. A commercial method has been developed for the separation and purification of the protease inhibitor from pooled human plasma; issues related to safety and clinical efficacy of this product are now under examination by the Food and Drug Administration. In addition, investigators are applying recombinant DNA technology to develop this protein as a potential for use in replacement therapy. Research and development in gene therapy promise yet another approach to prevent the genetic deficiency linked with emphysema. Studies are now being initiated on the function and regulation of the alpha-1-antitrypsin gene, and to develop an animal model of the human genetic deficiency for the antiprotease using genetic engineering.

Unfortunately, none of these therapeutic approaches are expected to be useful for the most prevalent form of this disease, emphysema caused by cigarette smoking in individuals with normal plasma levels of protease inhibitor. For these individuals, investigators are examining methods to directly deliver protease inhibitors to the lung itself. Although a number of synthetic inhibitors have been developed, tested, and proven effective in animals, they have not yet been used in humans as the inhibitors available to

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date are too toxic, too reactive, or too unstable to be considered safe for human use.

LUNG DISEASES

Question: We often hear about black lung disease, brown lung disease and white lung disease. What are they?

Answer: Black lung, brown lung and white lung are lay terms applied to several different occupational lung diseases. Black lung disease, or coal workers pneumoconiosis, results from inhalation of coal dust and gets its name from the black coal deposits seen in the lungs of its victims. The most important medical concerns are with coal workers who develop progressive, irreversible scarring of the lungs (fibrosis) and those who are at risk of developing complicating additional disease such as chronic bronchitis, increased susceptability to respiratory infections and emphysema. Brown lung disease, or byssinosis, is an acute reaction of the lungs to cotton dust. It usually appears in textile workers who have been exposed to the dust for several years. The initial symptoms of this disease are tightness of the chest, wheezing, cough, and low-grade fever. As exposure continues, the presence of symptoms progresses and if steps are not taken to limit exposure the development of severe chronic obstructive lung disease often results. Recently the term white lung has been associated with asbestos-related disease of which the most common form is asbestosis, an irreversible scarring of the lungs induced by the presence of asbestos in the lungs. Cancers such as carcinoma of the lung and mesothelioma are less common than asbestosis but have higher mortality rates. The term white lung disease was coined by asbestos workers whose x-rays displayed the white shadows diagnostic of the scarring or cancerous growth in their lungs.

Question: What are you doing about them at the Institute?

Answer: The National Heart, Lung, and Blood Institute (NHLBI) through the Division of Lung Diseases (DLD) is supporting research related to all three of these diseases. In one study involving about six thousand textile workers, NHLBI-supported investigators are determining the risk for developing chronic obstructive lung disease as a consequence of exposure to cotton dust in textile manufacturing. Support is provided to a number of researchers who are investigating the basic mechanisms which result in asbestosis. Many asbestosis patients have altered immune responses. In 1982, the DLD solicited applications for research on the basic immune responses underlying diseases such as asbestosis. Although the NHLBI does not support research directly dealing with black lung disease, it does support a great deal of basic research on pulmonary fibrosis, chronic bronchitis and emphysema, all of which can be applied to understanding the mechanisms in the lung that result in the various disease manifestations attributed to inhalation of coal dust.

Question: Now that alpha-1-protease inhibitor, also known as alpha-1-antitrypsin, has been classified as an Orphan Drug, what is the current status of its availability and potential for treatment?

Answer: Alpha-1-antitrypsin, which has the potential for the treatment of a rare form of emphysema, has been given the orphan

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drug status. A small fraction of the U.S. population, about one hundred thousand, suffers from a genetic deficiency resulting in synthesis of defective alpha-1-protease inhibitor. A majority of such individuals eventually suffer from emphysema early in life, especially if they smoke. Currently, there is no treatment available for this disease and patients usually die after suffering for one or two decades. One suggested approach to protect such genetically deficient persons from emphysema is supplementation with normal alpha-1-antitrypsin. Researchers have established that intravenous administration of normal alpha-1-antitrypsin, purified from human plasma, provides adequate levels of the inhibitor in the lung. According orphan drug status to this protein has encouraged the pharmaceutical industry not only to purify the protein from human plasma on a commercial scale, but also to develop procedures for its manufacture by the recombinant DNA technique. The classification seems to have also resulted in initiation of studies to evaluate safety and efficacy of the drug. At a recent public meeting, jointly organized by the Division of Lung Diseases and the Food and Drug Administration, experts discussed the replacement therapy in the context of patient population and criteria for safety and efficacy, and developed recommendations for the Food and Drug Administration on future course of action. As a result it is expected that a decision on licensing the drug for treatment of emphysema in the genetically deficient individuals will be made as soon as the human safety evaluation data are available.

If the human plasma derived alpha-1-antitrypsin is licensed for treatment, at best, it would be sufficient to treat only 8-10,000 patients, approximately one third of the patient population in need of the treatment each year. Scientists are now trying to manufacture this protein using biotechnology.

Question: It is often difficult to obtain medical help for patients who have a rare disease. Because so few people are affected, often times little research is done to study the cause, treatment, and prevention of these diseases. Does the Lung Program include any special programs to study rare lung diseases?

Answer: The Lung Diseases Program supports research related to several rare diseases where there are opportunities to promote better understanding of a given disease, or to develop better therapeutic and preventive interventions. Included among the rare lung diseases with active research programs are: idiopathic pulmonary hypertension, alpha-1-protease deficiency, neonatal respiratory distress syndrome, cystic fibrosis, and sarcoidosis.

Special initiatives have been taken in all of these areas in an effort to coordinate ongoing programs or to stimulate more research. Included among these are a registry for idiopathic pulmonary hypertension to attempt to find better methods for early diagnosis, follow natural history and possibly identify potential methods to arrest the disease process through drug interventions. Neonatal respiratory distress syndrome and cystic fibrosis are among the diseases under study in the Program's Specialized Centers of Research Grant Program in Pediatric Pulmonary Diseases. In 1984, the NHLBI joined the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases to initiate a special grant program on the "Metabolic Defect in Cystic Fibrosis."

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Research related to alpha-1-protease deficiency received considerable attention during the past year. Because it is believed that the genetic deficiency of alpha-1-antitrypsin in the lung leads to destruction of lung tissue causing emphysema, replacement of normal human alpha-1-antitrypsin has been suggested as one approach to prevent occurrence of emphysema in individuals suffering from this inhibitor deficiency. A commercially prepared purified human alpha-1-antitrypsin was recently developed and is currently being examined by the Food and Drug Administration for its safety and efficacy. Additionally, the Lung Diseases Program plans to implement a program in 1985 to develop an animal model of this disease using the newer techniques of genetic engineering. Such a model would greatly aid in developing therapeutic modalities, including gene therapy, to protect the genetically deficient individuals from emphysema.

PASSIVE SMOKING

Question: There has been a lot of discussion recently about the effects of second-hand, or passive smoking on the respiratory system of children. Is there any evidence that passive smoking is harmful?

Answer: Evidence that passive smoking is harmful to the respiratory system of children has now appeared in the scientific literature. A prospective epidemiologic study has revealed a seven percent reduction in the rate of lung growth in children whose mothers smoke when compared to children of nonsmoking mothers. Results of two additional population studies have now confirmed the finding of diminished lung function in children whose mothers smoke. Moreover, children of parents who smoke have been found to suffer from more respiratory illnesses during the first year of life. The medical significance of increased respiratory illnesses during infancy and diminished lung growth and function remain unclear. However, all these factors may exacerbate chronic airways diseases in later life. In addition, children growing up in homes where parents smoke are significantly more likely to become smokers themselves than children of nonsmoking parents.

ASTHMA

Question: What can you report regarding your Institute's efforts and of the current progress in the area of asthma?

Answer: Asthma is a disease which affects millions of Americans of all ages. The National Heart, Lung, and Blood Institute continues support of both basic and clinical research related to asthma with major emphasis on the mechanisms of bronchial constriction and mucus secretion, major problems of people who suffer from asthma. These studies are expected to provide improved understanding of the agents and processes causing bronchoconstriction and should make it possible to design more effective drugs. The research emphasis of investigators supported by the National Heart, Lung, and Blood Institute in the next few years is expected to be on the pharmacology and neurobiology of the airway smooth muscle and on the cells at the interface of air and the lung tissue in normals and asthmatic individuals.

Asthma is a disease uniquely amenable to preventive measures. Since only certain individuals seem to develop asthma, the inci-

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dence of asthma should decrease if such individuals could be identified and counselled to avoid the situations and environments that precipitate asthmatic attacks. Through support from the National Heart, Lung, and Blood Institute three asthma self-management programs have been developed. These programs have been well received by both the medical and patient community with highly encouraging results. For example, among people reached by these programs, there is evidence of reductions in hospitalizations, in emergency room visits and in days lost from school. Workshops have been held to teach health professionals how to conduct the asthma programs and to promote wide dissemination of educational materials on self-management programs to asthmatic children and their parents. These workshops have been conducted in collaboration with the American Lung Association and Boehringer-Ingleheim Pharmaceuticals, Inc. and are expected to be continued, and expanded, in the next few years.

ACUTE RESPIRATORY FAILURE

Question: Hospitalized patients being treated for infections or recovering from traumatic injury occasionally experience failure of their respiratory system. Apparently, the outlook for these patients is not very good. What programs does the NHLBI sponsor to improve the outcome in these circumstances?

Answer: Acute respiratory failure that develops in patients suffering from many kinds of infection or injury is known as the adult respiratory distress syndrome. This disorder affects an estimated 150 thousand people a year and is associated with a mortality rate of about 60 percent. The major goals of the Institute's program are improving the diagnosis and treatment of this disorder. Identifying acute respiratory failure in its earliest stages is important because treatment at this time is likely to be more effective than after the condition has progressed. Investigators supported by the NHLBI have found that the ability of lung cells to extract a naturally occurring mediator such as prostaglandin E1, from the blood is one of the first measurable changes in patients with acute respiratory failure. This finding may lead to a useful method of early detection. Improving the survival of patients with adult respiratory distress syndrome depends on understanding the cellular and biochemical changes that occur as the disorder develops. In patients with this condition, an enzyme known as elastase accumulates in lung tissue, where it appears to cause injury by destroying a number of proteins. Under normal conditions, free elastase activity is not found in the lung because it is inactivated by an inhibitor, but in patients with adult respiratory distress syndrome the availability of inhibitor appears to be reduced. Studies supported by the NHLBI are increasing our understanding of the imbalance between elastase and its inhihitor in these patients and should lead to ways of reducing this form of lung injury.

Many of the studies dealing with the adult respiratory distress syndrome are conducted at five Specialized Centers of Research in Acute Respiratory Failure, supported by the NHLBI. These centers represent a unique resource because of the multidisciplinary nature of their component projects, and because detailed laboratory studies of the syndrome are complemented by parallel clinical research in patients. Furthermore, because these centers have access to a population of patients who are at risk for development of this condition,

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they are able to conduct epidemiologic investigations to identify the clinical factors associated with development of the adult respiratory distress syndrome. These studies should improve the physician's ability to predict which patients will develop this condition, and thus, to prevent it or treat it more effectively.

SLEEP DISORDERS

Question: We often hear about sleep disorders affecting respiration to the point that breathing may temporarily stop. Can you tell me about this problem?

Answer: Much has been learned in recent years about sleep and the respiratory disturbance during sleep known as sleep apnea syndrome. In healthy humans, breathing decreases during sleep and becomes somewhat irregular with short periods of apnea (cessation of breathing for longer than ten seconds). In contrast, patients with sleep apnea syndrome may spend much of the night not breathing, with episodes of severe oxygen deprivation, and experience troubled sleep, frequently interrupted by arousals. The hallmark of the syndrome is excessive daytime sleepiness and diminished quality of life during daytime. Generally, sleep apnea is seen in males of all ages, post-menopausal women and the elderly. Most of the adult patients are obese, those that are not usually have anatomical abnormalities that narrow the airways. The interruptions that occur in breathing during the night have been divided into two types, central and obstructive apneas. In the less common central apnea, there is no sign of respiratory activity, suggesting some central nervous system control mechanism is at fault. In obstructive apneas, respiratory efforts continue but there is no flow of air at either the nose or mouth. It is believed that a block in the upper airway occurs that prevents the movement of air into the lungs. It is now thought that the cause of this blockage is the failure to produce adequate activity of the muscles that expand the upper airway during inspiration.

Question: Are there solutions?

Answer: If the cause of the obstruction is anatomic, such as enlarged tonsils and adenoids, surgical correction of these abnormalities often cures the condition. If no anatomic obstruction is present and if the obstructive apnea is mild, weight loss, mechanical ventilation, and use of respiratory stimulant drug therapy has been found to reduce the episodes of apnea, and often cure the condition. In severe cases, more aggressive surgical procedures and drug therapies are attempted. However, the efficacy of most of the proposed medical therapies is not clear-cut and is based on the understanding that current medical approaches yield mixed results at best. Because of our lack of understanding of the mechanisms of sleep apnea, and since more than 5 million Americans have been diagnosed with this disorder, the National Heart, Lung, and Blood Institute plans to bring together the leading scientists and clinicians in the field for a workshop to discuss and make recommendations regarding current and new therapeutic approaches to respiratory disturbances during sleep.

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NAS/IOM STUDY

Question: What is your reaction to the National Academy of Sciences Institute of Medicine's report on the organizational structure of the National Institutes of Health? What lessons from the National Heart, Lung, and Blood Institute experience (i.e., incorporation and operation of the Lung Program) could be useful to other Institutes?

Answer: The Institute of Medicine report on the organizational structure of the National Institutes of Health addressed three general areas. 1) organizational evolution, 2) NIH and the health policy environment, and 3) ensuring a manageable structure for the NIH. The second and third of these general areas have to do with proposals concerning levels of the bureaucracy above and beyond that of the individual institutes. The first general area, however--that of organizational evolution--provides recommendations for activities that are within the sphere of responsibility of the NHLBI. Such recommendations concern ways to enhance the responsiveness of the NIH to biomedical needs and opportunitites, by dialogue with the scientific community, by strengthening planning, and by organizational modification short of the creation of new institutes. These recommendations are thoughtful and helpful and the changes suggested have already been implemented by the NHLBI during recent years. A dialogue with the scientific community has been formalized in a series of public hearings, held by the NHLBI in Washington, DC, San Francisco, New Orleans and Chicago in 1983, in which the biomedical community and the public have been informed about fiscal trends in the funding of NHLBI research and research training, and in which an opportunity has been provided for the Advisory Council and the Institute staff to hear directly from those interested in, and concerned about, the NHLBI extramural programs. These hearings are to continue in 1985. Institutional planning has been strengthened by the adoption of a biennial implementation planning process, which provides the flexibility to respond quickly and effectively to legislative mandates and broad health objectives established by the Department with the full involvement of the advisory committees and Council. Finally, the NHLBI provides a prototype of limited organizational modification in the form of the establishment and incorporation of the extramural Lung Program. Rather than the creation of an independent entity to embrace diseases of the lungs, the inclusion of a Lung Program within the NHLBI has provided the necessary focus for these activities, but, at the same time, has brought into juxtaposition a number of health problems having a great deal in common. Diseases of the heart, lungs and blood share much by way of underlying mechanisms, and as modern molecular biology and genetics begin to throw light on some of these, the wisdom of an integrated approach becomes more apparent.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: Minor reductions in administrative costs can be achieved internally by streamlining in-house procedures, where possible, and by contracting-out labor intensive support services.

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Competitive research grant applications could be strictly held to page limit restrictions. Such restrictions would decrease the time required for review, but the limitations would be set so that research proposals could be concisely but adequately, presented.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: Yes, the Institute employs three management specialists who, in addition to other responsibilities, devote substantial time to conducting management studies and reviews of administrative operations to improve efficiency. They also monitor the state-of-the-art in management technology so that Institute management is prepared to take rapid advantage of new technologies that offer cheaper, more efficient ways to accomplish tasks.

Besides these specialized staff resources, functional managers are responsible for ongoing management improvement efforts within their respective work area. In addition, the NHLBI has recently established a committee of Division and office Directors to identify and evaluate ways to improve productivity.

The Institute, with the concurrence of the National Heart, Lung, and Blood Advisory Council, has taken steps to award carefully selected meritorious research grants for periods of 5 years, and sometimes 7 years, when initial review groups have recommended fewer years of support. This practice decreases our administrative burden and the burden of grantee personnel by decreasing the frequency of competitive applications that would otherwise have to be developed and reviewed.

In addition, the National Heart, Lung, and Blood Institute is hopeful that a proposed consolidated office building will be made available to house all NIH extramural administrative staff in one location.

Such a facility would provide an environment of communication and cooperative participation leading to much greater administrative saving.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: Recent changes in procedures for responding to Privacy Act requests for summary statements have resulted in the elimination of one full-time position used primarily to fill those requests. Increased use of wordprocessors, computers and other electronic aids have contributed productivity gains. We have reviewed delegations of authority to place responsibilities at more appropriate levels. We have instituted controls over the filling of vacancies to insure that only essential staff members are replaced.

During the past year, the Institute has also sought to meet its increased workload by contracting-out some support services or by using other than full-time employees (temporary, part-time) to meet program demands.

Question: What measures have been developed to help ensure the

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equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: Primary emphasis in cost reduction efforts has been placed on streamlining those procedures and processes which support peer review rather than on the peer review activity itself. Although we continuously seek opportunities to improve scientific review, very little of the peer review system as managed by NIH and operated by NHLBI has been altered. Our aim continues to be to improve effectiveness and efficiency without jeopardizing the recognition of scientific excellence.

Questions Submitted by Senator Daniel K. Inouye

BEHAVIORAL MEDICINE

Question: The Committee has been impressed with the NHLBI's efforts in prevention and various behavioral medicine initiatives, such as recommended in HEALTHY PEOPLE. The Committee would appreciate receiving an up-dated report on the Institute's plans in these area.

Answer: The NHLBI is continuing its efforts to understand the interaction of behavioral and biomedical factors in the prevention and control of disease. In addition to substantive overall increases in research support in biobehavioral research in 1984, the Institute is funding several new initiatives in 1985.

Two of these initiatives are oriented toward understanding the basic mechanisms associated with the contribution of "stress" to cardiovascular disease. The initiative, entitled "Stress, Neuropeptides and Cardiovascular Disease," will attempt to establish the neurological mechanisms through which stress affects the normal functioning of the heart. The role of exercise as a potential inhibitor of the effects of stress on the development of coronary artery disease will be investigated through an initiative entitled "Exercise, Stress and Atherosclerosis."

Efforts to enhance smoking cessation in cardiovascular disease patients at point of diagnosis will be given impetus by the initiative, "Smoking Cessation in Patients with Cardiovascular Diseases."

The three community-based cardiovascular risk-reduction programs funded by NHLBI continue to make excellent progress. Although the final results concerning program effects on morbidity and mortality must await completion of these studies (the earliest is scheduled to end in 1988), preliminary results concerning changes in risk behaviors in the target communities appear particularly encouraging as compared to the control populations under study.

As the reduction of elevated blood pressure has become a major public health concern, the Institute has been actively exploring various treatment strategies to effectively lower and maintain blood pressure within normal limits. The Hypertension Intervention Pooling Project is aggregating data from eleven independently funded studies of behavioral and behavioral-pharmacologic combination interventions to determine the relative effectiveness of such procedures.

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Recent working conferences, including Stress Reactivity and Cardiovascular Disease (co-sponsored with the University of Pittsburgh) and the American Heart Association Working Conference on Behavioral Medicine and Cardiovascular Disease (co-sponsored by NHLBI) have served to highlight both the current accomplishments and directions for future research in behavioral medicines on cardiovascular disease. For example, the recent inconsistency of results linking the Type A behavior pattern to coronary heart disease was reviewed by leading scientists in an effort to clarify this issue. The analysis of Type A behavior into more discrete components has highlighted specific behavioral factors (e.g., hostility, cynicism and unexpressed anger) as being consistently related to the prevalence of coronary heart disease while such other attributes of Type A (e.g., time urgency, competitiveness, and "workaholism") have demonstrated little or no association with coronary heart disease. Discussions during the conference on cardiovascular hyperreactivity also illustrated a consistent association between levels of cardiovascular reactivity and the hostility and anger dimensions described above.

Future research efforts will be directed toward better defining the interactive effects of behavioral and biological variables in terms of stimulating or inhibiting the development and progression of cardiovascular disease. These research efforts will particularly highlight the role of cardiovascular hyper/hyporeactivity in terms of measuring the effect of these interactions and its role in the disease process.

In the area of smoking, a major problem is not smoking cessation, per se, but maintaining cessation. Therefore, NHLBI will conduct a workshop on smoking relapse in July 1985, at which research scientists will discuss their current investigations on the factors that relate to smoking relapse. By identifying the personal and situational variables that predict smoking relapse, the design of cessation programs should be improved.

Based on recent investigations, social support and social networks appear to play important roles in the area of coronary heart disease. The processes by which support influences coronary heart disease, however, are not well understood. In the future, therefore, NHLBI plans to direct attention toward better understanding the relationship between social support and coronary heart disease.

CENTERS PROGRAM

Question: We understand that limitations on the research centers you may support has been proposed by OMB. What effect will this have on your ability to support areas of research of high priority to the Institute?

Answer: The immediate effect of the 1985 limitation is that the NHLBI will delay initiation of its planned Specialized Centers of Research (SCOR) program in transfusion medicine. The Institute believes that the SCOR programs are especially useful mechanisms for significantly accelerating research in high priority areas where coordinated, multidisciplinary efforts are likely to produce rapid clinical applications of basic science advances. The NHLBI views transfusion medicine as an important clinical area; one

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in which basic research can substantially enhance the application and effectiveness of blood products and resources.

A restriction on the number of authorized centers scheduled for 1986 means that the Institute will have to choose between an additional delay of the transfusion medicine SCORs and impairing the effectiveness of the existing SCOR programs in hypertention and/or thrombosis, both of which are due for renewal in 1986.

Question: What advantages do Centers have in exploring a particular area of science?

Answer: The NHLBI centers programs provide the Institute with an invaluable complement to its portfolio of investigator-initiated research projects. They allow a concentration of resources, facilities, and research personnel on high priority research topics. The multidisciplinary nature of the individual SCORs and the emphasis on network coordination among the centers and with the Institute distinguish the SCOR programs from other research support mechanisms available to the Institute.

Question: How will these limitations affect the disease prevention/health promotion and behavioral medicine initiatives we have agreed in years past to be of high scientific and public health priorty?

Answer: In addition to their effect on the research effort in transfusion medicine, the limitations on centers may also retard the advancement of research in a number of other areas where the SCOR mechanism would be particularly applicable. Research in nutrition and its relation to disease prevention and health promotion requires multidisciplinary teams and close collaboration among basic scientists and clinical investigators. Similar conditions are required for advances to be realized in the prevention, diagnosis and treatment of dysrhythmia and sudden death, pediatric heart disease, pediatric anemia, hemophilia, peripheral vascular disease, deep vein thrombosis and pulmonary embolism. Each of these areas is an important medical problem and is, therefore, a potential subject for a future SCOR program.

DIET AND HEART DISEASE

Question: Increasingly, efforts are being made by your Institute and voluntary organizations like the American Heart Association to alert the public to the levels of sodium content in foods they consume. Would all hypertensives and potential hypertensives benefit from reduced sodium consumption?

Answer: Persons vary in their sensitivity to sodium and their blood pressure response. Several studies have shown a large proportion of hypertensive patients to be at least somewhat sensitive to sodium and to have lower blood pressure on a sodium restricted diet. The value of sodium restriction and other nonpharmacologic measures is under continuing investigation. The 1984 Report of the Joint National Committee on Detection, Evaluation, and Treatment of High Blood Pressure states that moderate sodium restriction, to about two grams of sodium, may reduce elevated blood pressure. "Although only certain patients with hypertension may respond, most research

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shows there is no hazard from moderate sodium restriction, and it may reduce the degree of potassium wastage associated with diuretic therapy."

Question: What is the NHLBI doing to further research on the relationship between nutrition and cardiovascular diseases?

Answer: Traditionally, the NHLBI has provided support for nutrition research through individual research projects, clinical trials, and research training. Because of future needs for the prevention, treatment, and control of cardiovascular disease, we have expanded our efforts, and in October 1984 issued a Request for Applications for Research in Nutrition and Cardiovascular Disease to include basic, clinical, behavioral, and demonstration and education research. These program grants will support cooperative research projects based on a common theme. Cardiovascular disease research scientists and those working in nutrition research and other areas of expertise will be brought together in collaborative efforts. This will lead to interaction within the institutions and provide stimulation to further cardiovascular disease nutrition research in general, and facilitate a more efficient transfer of new research information to teachers and practitioners in those and other institutions. In another program, we have just funded four grants to study sodium sensitivity and blood pressure response. The objective of this special grant program is to support research to identify the mechanisms and characteristics that determine sodium sensitivity by studying the effect of sodium loading on blood pressure in individuals within the normal range and in persons with essential hypertension.

In addition we have several other nutrition research efforts. A study is underway to determine whether increasing dietary potassium or lowering the sodium/potassium ratio reduces blood pressure. Both men and women with diastolic blood pressure of 85-94 millimeters of mercury and not on other forms of therapy are being enrolled. Another study, the Trial of Antihypertensive Intervention and Management (TAIM), is examining the optimal management of mild hypertensive patients, including the study of certain behavioral variables. Two diet regimens (weight loss and decreased sodium/increased potassium) and a control and two drug regimens and a control are included. Contract proposals are being reviewed now in response to a solicitation released in October 1984 on the development of obesity in young black and white females. The research goal of this program is to determine whether the black-white difference in the development of obesity in females during pubescence is due to psychosocial, socioeconomic, and other environmental factors, and whether these differences in the development of obesity are associated with other cardiovascular heart disease risk factors, such as hypertension which is more prevalent in blacks.

Question: In 1976, the NHLBI was directed by Congress to conduct a pilot program designed to test the effectiveness of large-scale statewide coordination efforts in controlling hypertension and reducing the mortality associated with related diseases. What is the present status of the program?

Answer: Four of the states have completed their programs and submitted final reports. On the basis of the sample surveys done

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after 3 to 3 1/2 years of coordinated interventions, two of the states showed definite improvements in the proportion of hypertensives aware, treated, and controlled. The other two, which were states with larger populations and higher levels of blood pressure control at baseline, showed improvements in awareness and knowledge; and control rates were improved in certain target groups, but over all the population, the control level did not show a significant shift. In their follow-up surveys during 1981 and 1982, each of these four states had higher levels of control than the nation as a whole based upon the findings of the second Health and Nutrition Examination Survey (1976-1980). Using the same criteria for control, (i.e., less than 140 systolic and less than 90 diastolic), the national level of control is 11 percent and these four states range from 16.4 percent 24.5 percent.

An evaluation project to contrast coordination efforts in these four states is currently underway by an independent contractor. The final three states which were funded 2 years later than the first four will submit their final reports in 1985, and it is hoped an evaluation project to compare efforts and results in these states can be done beginning in 1986. In addition, trends in stroke mortality from at least 5 years before to several years after the projects will be reviewed and compared with neighboring states and the nation as a whole.

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NATIONAL CANCER INSTITUTE

STATEMENT OF DR. VINCENT DeVITA, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

JOHN P. HARTINGER, FINANCIAL MANAGER, NATIONAL CANCER INSTITUTE

PREPARED STATEMENT

Senator WEICKER. We will now hear from Dr. Vincent DeVita, Director of the National Cancer Institute, the largest Institute at the NIH, requesting a budget of $1.126 billion which is a decrease of $57 million in fiscal year 1985 appropriated amount. Dr. DeVita, welcome.

Dr. DEVITA. Thank you, Senator Weicker.

I would like to submit my full statement for the record and excerpt a few comments for you.

[The statement follows:]

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STATEMENT OF DR. VINCENT DEVITA

I appreciate the opportunity to present the progress and accomplishments of the National Cancer Program.

Fueled by the National Cancer Program resources, researchers have now attained an understanding of the cancer process which has enabled them to create a blueprint of its operation. This blueprint gives us unprecedented understanding of cancer biology and developmental biology which will lead us to new opportunities in the control of cancer.

We now believe that all the abnormal aspects of the cancer process parallel a normal process essential to our earliest development. Cancer only occurs in multicellular organisms. The human body, such an organism, develops in systematic fashion from a single cell to a group of cells, to an embryo, and finally to an adult organism. During the time that our cells grow quickly, there is unrestricted growth. But when tissues and organs reach their specified size, genes that control cell growth shut down uncontrolled growth and equilibrium is reached. Such growth control is vital to the greater good of the organism.

It is increasingly clear that cancer, which is by definition the unrestricted growth of cells, represents a loss of the regulation of cell growth and a reversion to the unrestricted growth pattern common in embryonic life. We now believe that cancer cell growth is probably controlled by the group of genes, referred to as oncogenes, which appear to be altered versions of the normal genes involved in early development. In the cancer process, these genes appear once again be turned on due to a variety of causes, such as relocation to different sites on our chromosomes, viruses, radiation or chemicals. Intense research is under way to characterize the 24 oncogenes we have identified to date and their protein products, for we believe the production of these abnormal proteins may result in malignancies. Recently, NCI-supported researchers have found that some oncogene products are directly related to factors that are known to switch on the unrestricted growth of cells.

A second process observed in normal embryonic development is that some cells must travel from one site to other sites and become seed cells that form various organs of the body. These cells then specialize or "differentiate," and acquire the capacity to carry out tasks of one organ, such as the liver, lung, or kidney. Abnormal migration of cells is dangerous in the developed human.

In the cancer process, the migratory capacity of cells appears to be reactivated, and cancer cells travel from the primary cancer through the bloodstream, developing secondary deposits in other parts of the body. These deposits are known as metastases. Such metastatic cancer cells invade and crowd out normal tissues in vital organs such as the brain, liver and lungs, and are the major cause of death from cancer. Since most cancer patients die from metastasis, not their primary tumor--a poorly appreciated fact--it is essential to understand and then block the way cancer cells metastasize. Recently, researchers have discovered important biochemical mechanisms involved in the metastatic process. Most recently, they have identified specific genes associated with this process, by identifying

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differences between the genes of cancer cells that do spread by migration and those that do not.

This means that, for the first time, we have a model system and thus a scientific handle to study ways of interfering with deadly metastases. Opportunities thus lie before us to block cell transformation and growth, and invasion and metastasis, the entire spectrum of the cancer process. For example, materials are being developed that can block the function of oncogenes. And, in experimental systems, scientists have been able to inhibit the receptors of the protein laminin used by cancer cells to stick to membranes as they prepare to migrate, thereby preventing cancer cells from invading other tissues. Our new understanding of the cancer process offers a paradigm change in cancer etiology, diagnosis, treatment and prevention--our ultimate goal. This new understanding was made possible by such new biotechnologies as recombinant DNA and monoclonal antibodies, developed by support of basic research which remains our first priority. The rapid, practical application of these research findings is also essential to save lives.

Our most recent statistics indicate that now over 50 percent of patients with serious cancers are curable. The resources invested in the National Cancer Program will continue to improve the outlook for all cancer patients.

I would like to briefly highlight past accomplishments and current plans in major research areas:

Cause and Prevention

- A major achievement last year was the discovery by NCI scientists that HTLV-III, one of the family of human viruses known as human T-cell leukemia/lymphoma virus, is the cause of AIDS. Diagnostic tests to identify the presence of the virus have been developed to protect the Nation's blood supply, and research is under way at our Frederick Cancer Research Facility to develop a vaccine. We believe the number of cancers caused by viruses has been underestimated. Research on HTLV-III has also stimulated renewed interest in the field of human cancer viruses--and this will be an area of increased research emphasis. For example, because of new technology, recent studies indicate that some strains of papillomaviruses, which also cause human warts, are the likely cause of cervical cancer, not herpes virus II as once thought.

- It was in using viruses as research tools that oncogenes were first discovered. Research on oncogenes and their protein products which cause cell transformation, continues to provide new details of the multi-step cancer process. With recombinant DNA technology, we can scrutinize the molecule DNA--which makes up the building blocks of genes--cut and splice it, identify changes in structure and use pieces of DNA as "probes" to find similar sequences in other cells. The arrival of NCI's new supercomputer will speed advances in our knowledge of oncogenes and their proteins. This knowledge will help us to design specific inhibitors to block their action.

- There are promising methods for identifying individuals at high risk for cancer, so that by changes in lifestyle or other interventions, cancer might be prevented. Most cancers have now been identified to have a chromosomal abnormality. (Genes are located on

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chromosomes.) Chromosome breakages that allow an oncogene to be relocated and "switched on" have been associated with human lymphomas and leukemias. Laboratory methods have been developed to detect "fragile sites" on chromosomes that may indicate increased susceptibility to breakage and rearrangement of key genes, and new assays can measure the damage done by the interaction of an individual's DNA with minute amounts of chemical carcinogens.

- Efforts of NCI's cancer control program are building momentum in cancer prevention. Chemoprevention research continues to identify chemicals and other agents capable of preventing or reversing the process of cancer; and nutrition research seeks to identify foods and dietary habits that may either induce, promote or inhibit cancer. Currently, NCI is supporting 26 clinical trials with chemopreventive agents or dietary factors believed to interfere with cancer progression in people with precancerous conditions, or at high risk for certain cancers. For example, folic acid is being studied in women with cervical dysplasia to try to prevent cervical cancer; and low-fat diet is being studied in women at increased risk for breast cancer in an effort to prevent it. In addition, a major prevention awareness program is under way, focusing on dietary modifications (particularly the increase of fiber and decrease of fat in the diet), and smoking cessation in efforts to reduce the incidence of several major cancers.

- The recently identified potent colon mutagen, fecapentaene, found in humans at high risk for colon cancer, has now been synthesized to provide sufficient material to test its role in the development of colon cancer. These studies will begin soon. Precursors involved in formation of this substance as well as ways to inhibit its formation will also be explored.

Diagnosis and Treatment

Recombinant DNA techniques and monoclonal antibody technologies that have contributed so much to discovering the blueprint of cancer, now hold enormous promise for rapidly diagnosing and characterizing tumors and for treating patients.

- Specific DNA "probes" are being used to identify genetic alterations in tumor tissue. The presence of oncogenes can be detected and the amount of their gene products measured. Correlations between the amount of oncogene product(s) and the prognosis of an individual patient will be studied. At the same time, sophisticated computerized programs for cell image analysis are being used to study isolated cancer cells, and these analyses are being automated for more rapid diagnosis.

- Monoclonal antibodies, designed specifically to home in on cancer cells, are being applied directly to biopsy samples to aid in tumor characterization. These antibodies, which can be tagged with radioactive tracers, are also showing promise in clinical studies to detect extent of disease (including hidden metastasis) in patients with colon and other cancers. Monoclonals have helped to distinguish one type of lymphoma from another. It is important to diagnose cancer early and accurately so the best treatment can be chosen. Two new markers to detect prostate cancer are among those that will be studied this year.

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In the treatment area, unrestrained local tumor growth may be controlled, as it has been for years, by removing the primary tumor mass (surgery and radiotherapy). Metastasis can be controlled in many patients with systemic therapy (chemotherapy or biological response modifiers), but this remains the greatest challenge. New understanding of the cancer blueprint allows new approaches and unprecedented opportunities for cancer treatment. Supercomputer technology is expected to help in the design and synthesis of new drugs directed at oncogene targets. The same prospect should hold true for "metastasis" genes and their products as they also are identified and studied. We hope to be able to predict which tumors will spread and which will not, seek out hidden metastases, and design treatments tailored to the individual. As mentioned earlier, researchers have already been able to stop metastases in animals.

Meantime, collaboration between surgery, radiation therapy, chemotherapy and therapy with biological response modifiers continues to improve the outlook for cancer patients:

- Combination therapy has allowed trends towards less radical surgery, supplemented by chemotherapy and radiotherapy, for patients with breast, rectal, prostate cancers, and extremity sarcomas. In fact, segmental mastectomy with radiation for early-stage breast cancer now appears to be an equivalent treatment to modified radical mastectomy. This year, a national study begins of a new, promising, minimally toxic, combination of antihormonal agents to treat prostate cancer.

- Chemotherapy has, for the first time, demonstrated new success in hard-to-treat tumors, like lung cancer and (combined with radiotherapy) pancreatic cancer.

- Surgery has now been used in a new way successfully to remove lung and liver metastases and cure some patients with advanced colon cancer and sarcomas.

- Promising results have also been seen in early studies from use of monoclonal antibodies to treat pancreatic cancer.

- An exciting development has occurred in breast cancer. A recent review of (early-stage) breast cancer studies worldwide now clearly shows that chemotherapy and hormonal therapy substantially decrease mortality. Early treatment with chemotherapy is seeing success in lung, breast, rectal, head and neck cancers, and childhood sarcomas. Progress is also being made in understanding and planning therapy to "outsmart" certain metastatic cancer cells that become "intuitively" drug resistant.

- Studies of biological agents, such as Interleukin-2, interferon, and monoclonal antibodies are providing interesting early results. This year, monoclonals will be coupled with powerful radioactive substances that emit alpha particles, or with toxins or drugs, in clinical trials for the widest testing to date.

Last year, based on what we already have in hand, we set a goal for the year 2000: to reduce the Nation's cancer mortality rate by 50 percent through better screening, diagnosis, treatment, and prevention of cancer. Never before has the pace of progress been so rapid. To foster information transfer from the laboratory bench to

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the patient's bedside, we have developed a network that links basic science laboratories, cancer centers, cooperative groups of clinical researchers, community oncologists, and practicing physicians. There is now wide access to PDQ, a new computerized database which provides information on the latest cancer treatments to physicians nationwide. This year, we will continue to expand the network through cooperation with state and local governments and private industry.

Mr. Chairman, the 1986 budget request for this Institute is $1,126,012,000, a decrease of $64,297,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985, this Institute will fund 790 new and competing grants, of which 135 will receive 3 years of support. In addition, we will fund 59 centers, of which 1 will receive 2 years of support. I will be happy to answer any questions.

THE CANCER PROCESS

Dr. DeVita. This has been a good year for cancer research. We described it as going from a black box to having a blueprint of the cancer process in front of us. What we have now realized is the cancer process is really a recapitulation of processes we use in embryonic development that can arise again when we get older. The uncontrolled growth that is cancer is something we believe is controlled by a small group of genes called oncogenes, which we told you about last year. In the past year, we have been able to work out, in experimental rodent models, the actual cascade of genes that are required to be activated in sequence to turn on certain kinds of cancer. This is a very promising advance in our understanding because we can use this knowledge to prevent, diagnose and treat cancer in ways we never knew before.

Cancer cells kill by metastasizing and invading vital organs. We found out this year, to our surprise, there are also genes which control the ability of cancer cells to metastasize. We are now cloning these genes. We are also able to block some of the material expressed by cancer cells in rodents, which gives us a model to block metastases and prevent death from cancer.

MAJOR ACHIEVEMENTS OF PAST YEAR

Molecular biology is moving to the bedside in these ways and represents a true paradigm change. In my statement I list a whole sequence of advances in the past year. I would like to list a few for you.

You have been discussing AIDS. After we met last year, Dr. Gallo reported the first formal proof that the disease is caused by the HTLV-III virus. Out of that came the blood test, as well as attempts to treat the disease and to develop a vaccine. Both efforts are moving along. Evidence developed through use of new DNA recombinant technology leads us now to believe the papillomaviruses, not the herpes virus II, is the cause of cervical cancer.

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We, in the past year, supported research in the isolation of T-cell receptor, and have been able to clone genes that should allow us to understand better why the immune system doesn't recognize a cancer cell as foreign. In clinical trials, we had a number of clinical trials turn positive. I want to emphasize the turn positive because studies which turned positive in the past have now influenced national mortality. The studies that turned positive this year could affect as many as 250,000 people and are in common cancers, including lung cancer, colon cancer, pancreas, head, and neck. This year, a consolidated analysis of all the breast cancer adjuvant studies worldwide was carried out. Results indicate that use of adjuvant therapy could lead to as much as an 8-percent reduction impact on national mortality. Also, an exciting new clinical trial is underway in prostrate cancer.

We even have 1 prevention trial out of the 26 that we support actually looking positive this year, a study of the ability of vitamin C to prevent the development of polyps in the colon. Polyps are benign tumors, but there has always been suspicion the benign tumors were associated with high risk of cancer of the colon.

All in all, it has been a good year and we are pleased with the progress made. Dr. Wyngaarden outlined the basis of the 1986 budget. I would reiterate $1,000,126,000, and it is based on the multiyear funding principle you discussed earlier. I will be happy to answer any questions which you have.

CHILDHOOD LEUKEMIA

Senator WEICKER. When I was stuck in the traffic on the George Washington Parkway, I was listening to a report on WMAL relative to treatment of cancer, in particular leukemia. The reporter was saying today about 90 percent of the children who have leukemia can expect the treatment to produce remission.

Dr. DEVITA. About 60 percent of all childhood leukemia is now curable. When I came into the field, a relatively short time ago, it was 3 percent of some subsets. It is 90 percent curable if you have the mild form, if you ever thought there was a mild form. Overall, it is 60 percent. A 1,500-percent increase since 1963.

PROGRESS AGAINST OTHER CANCERS

Senator WEICKER. Can you give us some other examples of other forms of cancer, as far as——

Dr. DEVITA [interposing]. I think one of the most important ones done recently is the adjuvant therapy for breast cancer. By adjuvant therapy I mean the use of drugs following the surgical removal of the breast tumor. By the way, the surgery has also changed, as you may have read recently in the newspapers. Since about 1973, we funded a whole series of adjuvant therapy clinical trials. Results from these now have been reported periodically. Now a worldwide analysis shows that the reduction in mortality in premenopausal women from adjuvant chemotherapy is about 26 percent and for postmenopausal women is

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about 20 percent. We are just now beginning to see this effect in our national data.

There is a 27-percent reduction in mortality premenopause in this country reflected in our surveillance, epidemiology and end results [SEER] data program, which we attribute in part to the widespread use of adjuvant therapy. We don't see it yet in the statistics for postmenopausal women.

Today, no man should die of testicular cancer, and mortality in this country for this disease has dropped by about 40 percent in the past decade. Mortality from Hodgkin's disease has dropped 85 percent in children and 58 percent in adults. Overall, childhood cancers have improved to the point where the 5-year relative survival rates have increased to about 57 percent. Well over one-half of childhood cancers are curable.

We are very, very encouraged about the new studies that turned positive because they are in the common cancers we have not been able to treat successfully in the metastatic state before. If the study results should continue this way, they should further reduce national mortality.

DIFFICULT CANCERS

Senator WEICKER. What do you find to be the most difficult? What are the most difficult problems in this area, the hardest nuts to crack?

Dr. DEVITA. The toughest cancer has been pancreas, and we now have two positive studies. Incidence of pancreas cancer is probably influenced by smoking, since the materials in the tobacco are absorbed in the blood stream and we find a higher incidence in people who are smokers. If you had 19,000 cases of pancreatic cancer, we would cure 300 with existing therapies. It is hidden way back in the abdomen, and is hard to find early.

Lung cancer has been another difficult cancer. There has been a statistically significant improvement in the survival of lung cancer patients over the past decade. However, because the number was so large, the improvement from 10 percent to 12 percent in relative survival rates is biologically not terribly important considering the large number of cases. However, one of the new adjuvant studies I mentioned is in lung cancer. We feel we can now make a bigger dent if the results of this study prove to be transferable.

We have been able to surgically remove and cure colon cancer to a certain degree. To get beyond the 40 percent is difficult. Now we have an adjuvant study that would make a big dent. I think one of the problems we have is public perception of curability of cancers. Many people don't realize some cancers have been curable to a certain degree. Getting these cancers beyond the plateau we hit in the 1950's has been difficult.

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BREAST CANCER TREATMENT

Senator WEICKER. My memory is not serving me well here. Weren't you involved very recently in this matter of breast cancer?

Dr. DEVITA. Yes; there is a group that is supported by the Cancer Program called the National Surgical Adjuvant Breast project, and they have been supporting a series of studies looking at both how to treat the tumor locally and how to use adjuvant chemotherapy. A series of studies that they started back in 1973 just reached a conclusion and the results were published last week in the New England Journal of Medicine. They have concluded that for women who have lumps of less than 1½ inches in diameter, a lumpectomy is as good as any surgical procedure.

Now a woman doesn't have to make a choice of her breast or her life. Lumpectomy with radiation leaves a satisfactory cosmetic effect. You cannot tell when a woman has had this operation, since it is a little incision. If they have a non localized tumor, you add chemotherapy. We have come a long way in increased survival and decreased mutilation. It was one of the most controversial areas in medicine. Most doctors have been trained to use more radical surgical procedures based on what we now feel are outmoded concepts of cancer. It is not easy to get the concepts out of the system.

Senator WEICKER. That is very important.

Dr. DEVITA. About 50,000 women a year are candidates for lumpectomies.

Senator WEICKER. Is the medical profession going to do the job of getting the word out, or is this something NIH is going to have to do?

Dr. DEVITA. We have a lot of help from the medical profession. For example, when the first set of studies came out in the mid-1970's, radical mastectomy had been the treatment of choice. Today radical masectomy is done less than 1 percent of the time. A modified radical was substituted and a lumpectomy has been gradually coming in. We estimate now about 15 percent of women are getting less than a modified radical, so there is a big way to go. Fifty percent of the women with breast cancer in this country should be candidates for lumpectomies. I think you will see the same change we saw with the dispensing of the radical mastectomy. It will take several years. Some physicians are skeptics. This is a 5-year study. People always say, wait until 10. When we get to 10, they will say wait to 15.

Our data indicates the results at 5 years have never significantly varied. We are quite satisfied in saying to the American women, you have a choice, lumpectomy is as good, will not influence your survival negatively, and can have a very nice cosmetic effect.

FUNDING PLANS FOR CENTERS AND COOPERATIVE GROUPS

Senator WEICKER. I understand you have had to implement funding plans below study section recommended levels for the past several years for two of your grant programs: The Cancer Center Program, and clinical cooperative research grants. Why did you have to take this action and what kind of reductions are being taken this year?

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Dr. DEVITA. Within the available budget, we always give the first priority to the support of the basic research. That leaves us with usually less available funds for clinical trials and the centers. We have worked with them to develop funding plans. In most cases, they have represented increases over the prior years but not paying at the recommended level.

For example, this year in the Cancer Centers Program, the average competing center will get an increase of 8 percent over the prior year's level. On average, competing centers were recommended for average increases of about 30 percent. They are getting much less than what was recommended, but they are getting an increase that is somewhat in excess of inflation. For cooperative groups we have not done as well. They are actually getting level funding or reductions from prior year levels. We have not been able to pay recommended levels in those two categories since at least 1980, maybe even earlier.

RESCISSION AND DEFERRAL

Senator WEICKER. How will your Institute absorb the proposed salary increase and rescission deferral?

Dr. DEVITA. Most of it has come from intramural funds. For us I think it was a total of $6.2 million.

SALARY LEVELS

Senator WEICKER. Since a large number of your senior-level scientists have expertise in technical areas with a high market value, for example, recombinant DNA, is your Institute having difficulty in attracting and retaining these individuals?

Dr. DEVITA. I think we are doing very well, considering we have never been competitive salarywise on any basis. However, we are being raided on a regular basis, and our fear of losing our scientists is currently rather high. We are in the process of recruiting several people for very senior positions, and we are having some difficulty maintaining a competitive stance because of the large differences in salary.

I hope we can succeed.

Senator WEICKER. Let's discuss that for a minute. With the talk of freezes, et cetera, et cetera, in the Federal area, it seems to me the last several years considering what is planned for the immediate year ahead would impact very particularly on all the disciplines within NIH because it seems to me at the same time your private pharmaceutical industry or research industry, et cetera, is accumulating record profits, obviously turning those over into salary, et cetera. Would you or Dr. Wyngaarden, anybody, Dr. Lenfant, care to comment as to how you are proceeding with this problem in personnel and salaries?

Dr. WYNGAARDEN. As Dr. DeVita said, the salary levels have not kept pace in NIH with those in the academic world or certainly with those in industry, but there are many advantages to the scientist at NIH. Today we still have success with recruiting. But as the differential becomes greater, the problem becomes greater. As you may know, the

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Packard Committee spoke to this issue and made some recommendations which are being addressed by the OSTP. I don't know what those recommendations would be, for renumeration for the chief scientists. We have lost a number of key people in the last 5, 6, 7 years. We have lost a number of postdoctorals who train at the NIH, but we don't necessarily consider those losses as we train more than we possibly can find permanent homes for. However, as I have said, we have lost a few key people.

Senator WEICKER. What is the current salary level for senior level Ph.D.'s and M.D.'s?

Dr. WYNGAARDEN. I don't have that scale here, but for the senior level M.D., with maximum longevity and additional comparability allowance, it would be in the high seventies. I suspect that Ph.D.'s would be 10 less, approximately the sixties would be as high as we can go.

Senator WEICKER. The seventies and sixties in that area. How much do you get as the Director?

Dr. WYNGAARDEN. The same.

Senator WEICKER. How much do you get in——

Dr. DEVITA. Same. There is a lot of charm in working at the NIH. [Laughter.]

Senator WEICKER. In that sense, I admire all of you. I really do. Whether it is salaries or whether it is stock options, all the rest of them. I just feel I really am deeply concerned about some of these salary policies in effect right now, especially an area that demands just as much knowledge and precision and ability as in the private sector. What is the administration proposal in the budget vis-a-vis all of your personnel? Is there a freeze salarywise?

Dr. WYNGAARDEN. There is a proposal for 5-percent reduction in salaries. I think that would apply to everyone except those in the Uniformed Services. For example, I believe the Commission——

Senator WEICKER [interposing]. Five percent reduction of all of them?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. That is just preposterous; absolutely preposterous.

I want the staff to find out the equivalent positions we are talking about here, Mr. Merck, Mr. Myers, Mr. Sharp, all the rest of these people, I would like to know what they make, I really do. It is just absolutely ridiculous. I am going to have to continue here. There are other questions for response for the record. Are there any matters you care to touch upon in public that I have not asked—I covered quite a few other areas and will submit it to you.

AIDS

Dr. DEVITA. I mentioned the AIDS business. I only throw that in because there are some startling new things coming along. I suspect by the time we come back next year we may actually be able to tell you there are ways we can effectively treat the disease. We seem to be overestimating the time required to accomplish some of these things. The discovery of the virus and the development of that test are an example.

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We knew we would create confusion with the test because once you have a test you can define the natural history of the disease. It tells us how the disease develops and those things are usable in the way of developing a treatment program for AIDS.

The Institutes are very heavily involved in the area. We are frightened by the disease, but pleased by the progress we have been able to make in that area.

Senator WEICKER. Do you feel with some degree of confidence within the next several years we will be able to get on top of this thing?

Dr. DEVITA. We have a handful of drugs that, surprisingly, inhibit the proliferation of the virus. This means that if you can get the drugs into somebody who has normal lymphocytes which have not been infected, it might be able to prevent the spread of the virus and prevent them from getting the disease.

We also know that the receptor on the cell where the virus gets in is divided into five separate parts and are susceptible to blockage by monoclonal antibodies. These experiments may well be done by the time we see you next year. We have a testable vaccine we can put into animals to see if we can develop an antibody that will in fact protect. A testable vaccine is not guaranteed to work, but we have gotten to this point very quickly. Things are moving along at a dramatic pace because the tools the scientists are working with are so refined now that it doesn't take very long to do an experiment. You can ask a question and get it done shortly.

I am optimistic that we will be able to actually prevent the spread of a disease in an individual and ultimately prevent the spread among populations. How fast and who we vaccinate will depend a lot on some of the things we talked about earlier—how many people are really going to get the disease. There are estimates that 400,000 may have already been exposed to the virus. We are still learning, but we have got the tools. There is nothing like having the cause in your hands when you are facing a really deadly disease. My heart goes out to people who had to face tuberculosis without knowing what caused it; smallpox without knowing it was a virus. We are in much better shape.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much.

I will have other questions.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

FY 1985

Question: The OMB Directive proposes to limit the Institutes to 5,000 grants for FY 1985. I assume the decision on how to divide the cuts up was left to the individual institutes.

You are planning to reduce the renewals by 101 grants and new grants by 139. How did you decide upon the number cut from continuing research?

Answer: We made the decision on how to distribute the reduction in competing grants in the President's Budget request by considering anticipated renewal and new applications, their priority score, and the funds we would have available for competing business for the remainder of FY 1985. For the last few years, we have tried to balance the value of ongoing research payline cutoff at the same priority score for both new and renewal proposals. We do not consider the priority score alone as the determining factor about whether or not to fund a particular application -- we give considerable weight to whether NCI is already supporting similar work, whether the research proposed is on an important subject not currently under study, and whether the area of study is ripe for exploration.

Question: Of the 101 grants that will not be permitted to continue -- how many are involved in critical areas of cancer research?

Answer: We intend to take a very hard look at the grants that are just beyond the payline this year (as we do every year) so that the most promising research will receive funding within the budget level. In any year we have to choose among many interesting applications and hope to fund the ones which will contribute the most to our understanding of cancer in its many forms; such decisions are really no different than decisions we must make every year.

Question: How much money has already been spent on the projects that will not be permitted to continue? Is that money being wasted by not allowing the work to be finished?

Answer: It would be impossible at this time to identify the specific projects which would not be funded under the President's Budget plan for FY 1985. However, we can make an estimate based on the average cost of research grants. Using those parameters, the NCI would estimate $65 million is the amount already paid over the years to the research grants which are not going to be continued in FY 1985. The funds expended thus far on those grants has definitely not been wasted because we have gained considerable knowledge and insight during the course of these research efforts. Although some momentum may be lost in acquiring new knowledge in the areas supported by these grants, there is always the possibility that the investigators will compete successfully in the future and continue their work with future NCI funding or funding from sources.

The NCI will make every effort to continue the support for those grants with a record of demonstrated productivity.

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Question: Have you or are you planning to review these continuing applications for possible future funding?

Answer: We plan to give these applications consideration in FY 1986 along with other proposals received that will be competing. Basically, we are informing those applicants whose priority scores fall between 158 (our current payline) and 170 (our original payline) that they have the option of letting their current application compete against the funding availability in FY 1986 at their current scores (unfunded applications can be carried forward to the next fiscal year) or of submitting a revised application to try to achieve a better score with which to compete in FY 1986.

CENTERS

Question: I note that you are losing only one center by the OMB action. Is that correct? How did you manage that?

Answer: The NCI is planning to fund one less center than was expected in the appropriation because the formula on which the reduction in centers was made eliminated new centers. The appropriation had included funds for one new center in FY 1985 and that was excluded from the President's Budget.

Question: You are planning to spend $83.2 million on 59 Centers in FY 1985, but only $81.9 million on the same number in FY 1986.

Please explain how the savings will be applied and indicate the effect on program.

Answer: As you noted, the budget will support the same number of centers in FY 1985 and FY 1986. This might more easily be seen by comparing the two years at the "program level" -- the dollar level that will be available to support the program each year regardless of the year in which the funds are obligated. In FY 1985, the program level for Centers will be $82.473 million ($83.2 million minus the funds obligated for second year costs of one of the Centers). In FY 1986, the program level increases to $83.379 million ($81.9 million plus the second year costs) -- an increase in available funding of a little over one percent. Although the available funding increases modestly, the overall effect of the budget on the program is to support the competing centers in the program below peer-review recommended levels, a reduction of 53 percent from recommended levels in FY 1986. This occurs because the reviewers have been approving increases of 30 percent over current funding levels for competing Cancer Centers. Continuing (noncompeting) centers will be funded at commitment levels.

CANCER CENTER FUNDING LEVELS

Question: I understand that you have had to implement funding plans below study section recommended levels for the past several years for two of your grant programs: the Cancer Center program, and Clinical Cooperative Research Grants.

Why did you have to take this action?

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Answer: Within the overall budget levels we have been provided within the past several years, priority has been given to the support of research project grants. Because of this we have funded some programs at flat levels, others we have cut back, and others we have allowed to grow in order to take advantage of the tremendous breakthroughs achieved as a result of our basic research efforts during the past several years. Among the programs which have been allowed a limited growth are the Centers and the Clinical Cooperative Research programs. The reductions were made to keep more clinics open under the clinical cooperative research program and to fund more centers. At the time, those programs were better able than others to maintain a viable research and support effort with only a limited growth in dollars.

Question: What kind of reductions are being taken this year?

Answer: In FY 1985, the non-competing Centers and Clinical Cooperative Groups are being funded at the commitment of record level. In both programs, the funds remaining for competing grants are not sufficient to pay the appropriate number of awards at recommended levels. In the Clinical Cooperative Groups program the competing awards are being made at an average reduction of approximately 30 percent below recommended levels. For the Centers, the final review results are not yet in; and so, the final award levels are not certain. However, it appears that an overall reduction of nearly 20 percent may be necessary if NCI is to follow the directive not to further reduce the number of Centers funded in FY 1985.

Question: Why is your judgment different from that of the members of the study section panels?

Answer: The study sections are directed to evaluate the relative merit of the science proposed in a grant application and to consider whether the budget proposed by the applicant is appropriate to support the science that is recommended for funding. In a sense, the study sections are responsible for the more popular decision in the area of funding -- they say how much is needed to fund a particular piece of science, and their purview is limited to those applications submitted to them for review. As managers of the Institute's budget, we must decide how much we can afford within our budget taking into account all the programs vying for funds within the Institute.

Question: How did your advisory council react to this decision?

Answer: As a matter of fact, the National Cancer Advisory Board (NCAB) has been a tremendous help to us in making these funding decisions. Additionally, the BSC for each Division weighs similar budgetary decisions for review and input from the NCAB and NCI management for final decisions. We have presented them with the problems we must resolve in funding the Centers and Clinical Cooperative Research programs and their advice has been to maintain the balance between programs which we have achieved over the past several years. I should note that the NCAB does not like to choose between programs in this way, but they realize that these are the

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difficult decisions which we must make in the governance of science at the NCI.

BUDGET

Question: The budget that the National Cancer Institute can present to Congress, by-passing the review of the NIH and the Department equal $1.46 billion.

The budget you are presenting today equals $1.12 billion. Discuss the differences in the two budgets as to the impact on your goals for the Year 2000.

Answer: The By-Pass Budget was mandated by the National Cancer Act of 1971, P.L. 92-218 which stipulated that the National Cancer Institute should "...prepare and submit directly to the President for review and transmittal to the Congress, an annual budget estimate for the National Cancer Program...". This budget is developed in conjunction with the advice and assistance of the National Cancer Advisory Board and the President's Cancer Panel and reflects the collective professional judgment of this cadre of individuals.

The 1986 By-Pass Budget of $1.460 billion was developed to take fullest advantage of current knowledge about cancer control. Over the past decade significant inroads have been made towards curing and preventing cancer. Overall, there are five million Americans who are alive with a previous diagnosis of cancer. In three million of these patients, the diagnosis was made five or more years ago. There will be over one million new cases of cancer diagnosed in the United States in 1984; excluding the easily curable, and rarely fatal, skin and early cervical cancers, there will be 870,000 more life threatening cancers. Half of all patients diagnosed with this more serious cancer this year are curable, and the NCI now estimates that, based on what we know today, it should be possible to reduce cancer mortality by 50 percent of today's rate by the year 2000. These projections reflect the increasing treatability and curability of cancer as well as application of prevention measures made possible by both basic and clinical research. NCI developed the 1986 By-Pass budget at a level commensurate with these facts, which would have hastened the diffusion of state-of-the-art approaches to treatment. Secondly, NCI has in place a unique network which includes Cancer Centers, a clinical trials program (the Clinical Cooperative Groups), Community Clinical Oncology Programs (CCOP), Cancer Center Outreach Programs, and the recently instituted computerized physician data query system, PDQ. All of these activities will assist in the transfer of treatment advances to the community and thus impact on the year 2000 goal of reducing cancer mortality by 50 percent of today's rate.

NCI believes that the goal for the year 2000 is still valid. The highest priority programs will be supported. We believe that the previous estimates regarding mortality reduction may have been conservative and, in fact, we can attain this goal, even at the reduced level.

Differences in assumptions between the 1986 By-Pass of

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$1.460 billion and the Administration's budget of $1.126 billion follow:

Assumptions	
1986 By-Pass ($1.460 billion)	1986 Pres Budget ($1.126 billion)
- Fund 40 percent of competing research project grants at recommended levels. No multi-year funding.	- Fund 25 percent of competing research project grants. Multi-year funding impact reflected.
- Increase the number of cancer centers by 50 percent and provide funds closer to recommended levels.	- Maintain same number of centers as in 1985. Competing centers to be funded at 53 percent below recommended levels.
- Fund Clinical Cooperative groups at recommended levels and double their capacity.	- Competing groups to be funded at 28 percent below recommended levels; would reduce number of projects supported.
- Fund grant construction renovation at a $20 million annual level.	- Would maintain at 1985 level of $6.5 million.
- Expand prevention and community efforts within Cancer Control.	- Cancer Control to be maintained at about 1985 level.

(Dollars in Thousands)

	1986 OMB By-Pass	1986 Congressional Justification	Change
Research Projects	$ 649,203	$ 476,360	-$172,843
Centers	97,000	81,981	-15,019
Clinical Groups	68,556	49,279	19,277
Other Grants	26,075	19,782	-6,293
Subtotal, Grants	840,834	627,402	-213,432
NRSA	36,000	30,838	-5,162
R&D Contracts	176,728	141,824	-34,904
Intramural Research	216,254	199,664	-16,590
Research Management and Support	71,184	58,229	-12,955
Cancer Control	96,000	61,555	-34,445
Construction	23,000	6,500	-16,500
Total, NCI	$1,460,000	$1,126,012	-$333,988

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RESCISSION

Question: How will your Institute absorb the proposed
-- salary increase?
-- rescission?
-- deferral (Section 515 set-aside)?
What will be the effect of these cuts on intra- and extramural programs?

Answer: The FY 1986 proposed salary increase will cost $3,921,000, including $330,000 for increased costs of the newly enacted Performance Management Recognition System. This absorption will be met by redirecting funds previously planned for higher levels of employment and delaying purchases of equipment and supplies. The $4,362,000 rescission and $1,857,000 deferral reserved under Section 515 of the Treasury-Post Bill will primarily affect consultant services, printing and travel activities. All of these requirements will be absorbed within the intramural research, research management and support and cancer control programs. Essential and high-priority areas of scientific research within the cancer program will be maintained.

REPROGRAMMING

Question: Have you been forced by funding shortfalls to do any reprogramming in the past year?

Answer: Based on scientific opportunities and advancements the NCI has redirected some of its resources to meet high-priority programs needs.

Question: In what areas did this occur?

Answer: In 1985, we redirected approximately $3.9 million into the Institute's Acquired Immunodeficiency Syndrome (AIDS) research efforts.

Question: What programs were hurt by this reprogramming?

Answer: The source of these funds were obtained from several of the Institute mechanisms of support i.e., cancer centers, clinical cooperative groups, research project grants, clinical education and the research career program.

FULL TIME EQUIVALENTS (FTES)

Question: Given the increase in your intramural research program, how are you going to deal with the loss of 213 FTEs without having a substantial impact on program?

Answer: The 1985 funding for intramural research is estimated at $202.6 million, while the 1986 estimate for intramural research is $199.7 million. Incorporated in the 1986 estimate are the reductions for the five percent federal pay reduction and administrative reductions. The 1986 budget decreases full time equivalent workyears (FTEs) from the 1984 level for intramural research of 1,769 FTEs to a 1986 level of 1,556. The reduction of 213 workyears is being accomplished primarily through attrition

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with selective replacement according to our most pressing research priorities. Throughout 1985, each program area has been operating under varying hiring ratios which allow different proportions of vacancies to be filled.

Question: How many positions would you gain if students, trainees and special experts were dropped from the FTE count?

Answer: Students hired under the Stay-in-School program are not subject to the FTE ceiling at this time.

If special experts were returned to their previous ceiling exempt status, the Institute would be able to hire approximately 100 regular employees in the ceiling slots now encumbered by special experts. In addition, we could hire approximately 51 more special experts for a total of 151 experts as authorized by law.

Question: How much would this action cost?

Answer: The cost of an additional 100 ceiling employees and 51 special experts is estimated at $5,626,000 for salaries and benefits plus $800,000 for supplies and equipment.

SENIOR SCIENTISTS TURNOVER

Question: Since a large number of your senior-level scientists have expertise in technical areas with a "high-market value" for example, recombinant DNA, is your Institute having difficulty in attracting and retaining these individuals?

Answer: The NCI has been successful in recruiting and maintaining a staff of very high caliber, despite lack of competitiveness with the private sector in salary potential. However, the lure of increased salary and benefits in industry has resulted in some depletion of scientific and administrative talent, and fear of losing top flight scientists is currently very high. NCI is now in the process of recruiting several people for very senior positions, and is having some difficulty maintaining a competitive stance because of large salary differences.

Although NCI constantly recruits for high-level scientists in medical and scientific specialty areas through advertisement in professional and scientific journals, contacts with academic institutions, and announcements at major scientific conferences, top positions may remain vacant for long periods of time.

Question: What are the effects within the various laboratories when such a person leaves the Institute?

Answer: One of the great strengths of the intramural research program at NCI is the opportunity it offers to young scientists to consult with and receive advice from outstanding senior scientist working on the NIH campus. Young scientists embarking on the application of new biotechnology to problems in cancer research frequently encounter unforeseen problems with techniques and methodology. Each time we lose one of our leading scientists, a large number of junior scientists lose advice and

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guidance, and our programs sustain enormous, although unmeasurable, damage.

When senior level scientist with expertise in the newly emerging areas in biotechnology leaves an NCI laboratory, the NCI suffers in its ability to do cancer research. In one NCI division a senior level scientist with expertise in recombinant DNA methodology left recently, and his departure has had damaging effects on many of the division's research programs. In addition to losing his own research program in the molecular biology of blood coagulation, we have lost his expertise as a teacher and advisor for many young scientists in various other areas of cancer research. Another division in NCI has lost the chiefs of three out of its five laboratories in the Biological Carcinogenesis Program during the past two years. These senior scientists were responsible for providing the direction to large laboratories which were at the forefront of research in the rapidly moving area of molecular biology, as well as for carrying out their own research programs involving oncogenes, growth factors and lymphokines. The impact of their departure has been that one of the laboratories has been disbanded, another completely reorganized. Another NCI division has lost two Associate Directors, one responsible for directing the Radiation Research Program and a second responsible for leading the Biological Response Modifiers Program. As a result, critical intramural and extramural programs in radiotherapy and biological research suffered discontinuity while appropriate replacements continue to be recruited.

Question: What can NCI or Congress do to remedy the situation?

Answer: Most senior-level scientists leave NCI to accept positions with the private sector where both salary and other benefits are much higher than those offered by NCI. Therefore, it appears that an increase in salary rates and a salary system which would provide flexibility in fixing initial salaries and adjusting the rate, thereafter on an individual basis, would be helpful in retaining senior-level scientists.

Most universities and scientific/medical institutions pay all benefits for the scientists and often provide education for family members. Better federal benefits would be another asset for retaining the scientific staff at NCI.

Question: What is the current salary level for senior level Ph.D.s and MDs? How many of these individuals have you lost in the past 24 months?

Answer: Current salary levels for senior level Ph.D's is $37,599 to $67,940; for M.D.'s $45,398 to $68,700. Over the past 24 months NCI has lost 25 M.D.'s and 20 Ph.D's.

PDQ SYSTEM

Question: What is the PDQ system, and how do you expect it to impact on cancer?

Answer: The NCI's philosophy in developing PDQ has been to

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develop a system for the health professionals of the nation, who have a real and immediate need for up-to-date information about cancer treatment, but who do not have special training in using computers to retrieve this kind of information.

PDQ is the final link in the chain of advances of cancer treatment which stretches from the basic laboratory, to clinical research, to practicing physicians throughout the country. To the extent that we succeed in making this information available to any physician or health professional who needs it, we will be fulfilling the Institute's mission to improve the standard of health care in our nation. A few years ago, PDQ would not have helped many cancer patients even if the computer technology had been available. Patients needed to have enough resources in the general vicinity to serve them. Those resources exist now, in cancer specialists, cancer centers, Community Clinical Oncology Programs, and cooperative groups. In addition, particular strengths and expertise in certain tumors exist in geographically diverse locations in the country. So an important challenge within the National Cancer Program is to help cancer patients and their physicians to find the best sources of assistance and knowledge available to them.

The key words in PDQ are interactive and geographic. It allows a physician or other health professional with no prior experience in the use of computerized databases, to interact with the computer, choosing options from a list on the screen. From the starting point of a diagnosis of cancer, one can obtain a state-of-the-art overview of the disease, and locate an institution, colleague, or research study on a geographic basis. The kinds of data contained within PDQ, and the fact that it is kept up-to-date on a monthly basis, make it a useful tool for physicians who do not spend a major portion of their time treating cancer patients, and for the specialists who do.

PDQ contains three files. The cancer information file contains state-of-the-art treatment statements for all cancers by stage. The protocol files describes all open clinical research protocols funded by the NCI and others accepted by the PDQ editorial board. The directory file includes hospitals participating in NCI funded clinical research and those with American College of Surgeons approved cancer programs as well as the directories of medical societies whose members spend the majority of their time caring for cancer patients. The latter two files can be searched on a geographic basis.

Future PDQ enhancements include information on the modification of drug dose to be added to the protocol file. This will provide practical information on the appropriate management of patients who develop side effects. Also, we plan to add a link to the CANCERLIT file at the National Library of Medicine and a new file on drugs which will contain information such as: indications for use, dose and schedule and side effects.

PDQ is presently available to physicians through several channels, including the National Library of Medicine's MEDLARS system and the BRS/Saunders Colleague database. The MEDLARS system is available primarily through more than 2,000 medical libraries

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and health care institutions throughout the country, while the BRS/Saunders Colleague database is a subscription service accessible though a home, office or hospital computer. Access to PDQ on MEDLARS and Colleague is restricted to physicians and other health professionals. NCI is also negotiating with other private companies which want to offer PDQ to their clients. According to the most recent survey, conducted several years ago, about half of the nation's physicians had access to a personal computer in their home, office or a hospital. Because of the rapid growth in use of personal computers, that number has certainly increased, and will continue to do so. Detailed information on the use of PDQ is not yet available, but a full evaluation study is underway.

NCI has used various media to apprise the medical community of PDQ, its contents, availability, accessibility and cost. Presentations have been made to major medical meetings and a number of scientific and lay articles have appeared in journals and the press. In addition, a Hospital Satellite Network tele-conference was broadcast in January 1985 and picked up in over 80 hospitals, and more than 11,000 information kits have been requested.

Although PDQ is intended as a tool for physicians, patients and the public also have a place to go for the latest information on cancer treatment. Patients can call NCI's Cancer Information Service, toll-free, on 1-800-4-CANCER. They will reach trained counselors who use many information resources, including PDQ, to help them.

SUPERCOMPUTER

Question: I understand that you plan to purchase a supercomputer.

What will the computer cost?

Answer: The supercomputer acquisition will be carried out in a competitive procurement process. It is estimated that it could cost up to $10 million.

Question: How will it assist you in your research efforts?

Answer: Changes in molecules, typified by oncogenes and their proteins, are believed to lead to the disease of cancer. We can now determine at great rate the sequences of the subunits that specify these aberrant molecules. To be able to understand their altered properties we need to visualize the three-dimensional shape and dynamic activities of each of the newly described genes and proteins. The fastest way to gain information on these molecules is by supercomputer, which can accomplish in a fraction of a working day as much as an ordinary computer does in a month. This capability will put us in an improved position to use one of the most powerful methods for study of a new and unknown molecule, namely comparison with other oncogenes or to normal genes whose functions are already recognized, such as growth factors or regulatory enzymes. Once a clue to the altered activity is found, the supercomputer will aid experimental design of molecules for study in the laboratory with the aim of creating specific inhibitors or controlling oncogene expression. Large scale

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scientific computation will also assist the design of synthetic drugs, the development of theoretical analysis of oncogenic and treatment processes, the exploration of the genetics of cancer, and the wide ranging studies on fundamental scientific databases that will be needed to understand and control cancer.

Question: Will other institutes be able to share its time?

Answer: Yes, provision is made for availability of the supercomputer laboratory to investigators in other institutes and to biomedical researchers outside of the the NIH, as well.

CLINICAL TRIALS

Question: We understand that NCI's Clinical Trials' program is functioning a bit differently from the other institutes.

Explain the differences and tell us why it is different.

Answer: The NCI is unique within NIH in its extensive use of a variety of funding mechanisms to develop new anticancer drugs as well as in its support of a nationwide network of cancer centers, outreach programs, Community Clinical Oncology Programs, and cooperative groups for clinical trials. This network provides rapid and effective transfer of cancer treatment research advances from laboratory to clinic. For much of its support of clinical treatment research, the National Cancer Institute does not fund the operation of specific clinical trials at individual institutions. Instead, in order to achieve statistically valid results within a reasonable period of time, the NCI supports the conduct of the same clinical trial at a number of institutions which have joined together for this purpose. These institutions form clinical cooperative groups which perform cancer treatment research under the cooperative agreement mechanism. Each group is organized to provide the optimal structure for clinical researchers to collaborate in the design of clinical trials and to accrue patients most effectively for the testing of new and promising cancer therapies. For each cancer site, there may be numerous ongoing trials which test the efficacy of chemotherapy, immunotherapy, radiation therapy, or surgery. These trials are identified by individual protocols. NCI reviews and funds approximately 600 new protocols each year. In addition, support is given to previously approved protocols which continue to accrue or follow patients over time.

Clinical trials in a new area or in a new application of one of the traditional modalities of treatment (such as chemotherapy, radiotherapy, immunotherapy or surgery) generally result in multiple protocols. The funding and priority assigned to each protocol or group depend upon the scientific quality and clinical importance of the applications received for cooperative agreements, grants, and contracts as determined by individual scientific peer review. The NCI supports this structure of clinical research in order to provide the maximum amount of flexibility in clinical studies on cancer. Since cancer is over 100 different diseases treatable by several modalities (chemotherapy, radiotherapy, surgery, immunotherapy) there are literally hundreds of investigator-initiated ideas for research

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developed each year. Clinicians may bring these ideas to their cooperative groups where a protocol is written and mutually agreed to by the members and subsequently submitted to NCI for approval.

As mentioned above, depending on the nature of the trial, clinical research may be supported by either contract, intramural research grant or cooperative agreement. In cases where an initial evaluation of a drug is being done, contracts are the appropriate mechanism due to the explicit reporting requirements of the FDA in submitting an Investigational New Drug for approval. Grants and cooperative agreements are used to fund investigator-initiated research which requires less government staff involvement than contracts. These studies include combinations of various treatment modalities to improve the efficacy of the therapy.

Question: Are you requesting funds for new trials in FY 1986?

Answer: New trials contained within the 1986 President's Budget level total $12.3 million and are as follows:

	($000) FY 1986 Estimate
Cooperative Agreements	
- Intergroup study of regional limb perfusion in patients with high-risk melanoma.	$ 300
- Intergroup study on the treatment of metastatic prostate cancer using LHRH agonists with or without antiandrogens.	300
Grants	
- In vitro/In vivo correlations of differentiating agents in human malignancies.	400
Contracts	
- Phase I/II trials with immunoconjugates to monoclonal antibodies.	500
- Phase I clinical trials using combination therapy: Interferon, differentiating agents, interleukins, Lymphotoxin or tumor necrosis factor.	500
Intramural	
- Trials with 1) monoclonal antibody to Laminin receptors for prevention of metastases in breast cancer; and 2) clinical trials using monoclonal antibodies to the bombesin receptor in lung cancer patients where bombesin is considered an autocrine growth factor.	300

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Control

- Community Clinical Oncology Program 10,000

Question: What are your plans for future trials?

Answer: Future clinical trials will continue to be guided by areas of scientific opportunity. A number of unique clinical applications of basic research now in progress can be identified.

Lung cancer is one of the most common, fatal and least treatable cancers. It is also the only cancer which is rapidly increasing in incidence. A project aimed at the development and use of established human tumor cell lines has been approved and is being implemented at the Frederick Cancer Research Facility. Screening for new antitumor drugs using human lung cancer cell lines will begin this year. Concommitantly, work will begin to establish batteries of human colon and breast tumor cell lines. It is anticipated that using cancer cell lines of human origin will allow the identification of new anticancer drugs uniquely active in specific human cancers. Such agents will be expedited for rapid entry into clinical trials.

Recent observations have confirmed that adoptive immunotherapy -- the transfer of "educated" lymphocytes -- can result in dramatic responses in patients with highly refractory cancer such as melanoma and colon cancer. This trial incorporates the delivery of lymphokine-activated lymphocytes in combination with systemic interleukin-II. If these impressive early results are confirmed by ongoing research in the intramural NCI program, a more extensive extramural study will certainly be indicated.

The activity of alpha interferon in patients with non-Hodgkin's lymphomas and hairy cell leukemia has been confirmed. This observation will undoubtedly lead to further basic work in determining both the mechanism of action of this biological as well as the optimal biological response modifying dose. This work will translate into a vigorous testing of alpha interferon in combination with chemotherapy in patients with poorly-responsive lymphomas.

The identification of differentiating agents which can transform malignant cells into normal cells offers yet another novel approach to the treatment of cancer. Clinical trials are now in progress with HMBA, the most potent differentiating agent of its class. This work has been possible because of the development of new preclinical differentiating screens which will be used to discover other novel agents of this class for clinical trials.

The availability of monoclonal antibodies offers the potential of heretofore unprecedented specificity for a variety of human tumors including melanoma, breast cancer and lung cancer. Techniques are being developed to conjugate such antibodies efficiently with toxins, cytotoxic drugs or radioisotopes. As technology advances in pharmaceutical organization and the NCI, a large number of cytotoxic agents conjugated to monoclonal antibodies can be expected. Availability of conjugates between other antibodies and toxins produced by recombinant DNA techniques

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will also become available. Preclinical studies have already demonstrated considerable promise for selective antitumor effects by such monoclonal antibody-toxin conjugates. The degree of specificity of the immunoconjugates for tumor cells is much better than for normal body tissues, and thus these agents hold great promise for high tumor specificity as well as low systemic toxicity.

Major progress has been made in the biology of viruses and their relation to cancer causation in human. Human papillomaviruses (HPVs), DNA viruses, were recently found to be strongly associated with cervical carcinoma. Investigations have shown that HPV DNA can be detected in 80 percent of individuals with neoplastic lesions of the anogenital tract; HPV DNA has also been detected in tumor cell lines derived from cervical carcinoma. It is anticipated tht DNA hybridization methods may be useful in the screening and early diagnosis of cervical carcinoma and other anogenital tumors. Also, recent breakthroughs have occurred in the identification of human retroviruses causing leukemia, lymphoma, and Acquired Immunodeficiency Syndrome (AIDS). This recent and important discovery now allows for the testing of new drugs designed to inhibit the replication of this cancer-causing virus. Already, early clinical results in the treatment of patients with AIDS indicate that viral outgrowth can be specifically inhibited by Suramin, a drug which inhibits retroviral replication. It is anticipated that other promising agents (such as nucleosides and antiviral compounds) will be identified and again expedited toward testing patients. This represents the first opportunity for physicians to treat cancer by attacking its cause.

Question: Can you provide the Committee with an example of a complete clinical trial and its impact on the treatment of cancer?

Answer: The National Cancer Institute has supported a major clinical trial in breast cancer treatment which indicates that less disfiguring surgery may be as effective as removal of the entire breast in women with early stage breast cancer. Breast cancer occurs in 119,000 American women each year.

Researchers from 89 institutions cooperating in the study concluded that removal of the cancerous lumps and an adequate amount of normal surrounding tissue to ensure that the area is tumor-free in combination with local radiotherapy is appropriate for treating cancer patients with tumors four centimeters or less in diameter (about 1½ inches). Findings of the National Surgical Adjuvant Breast Project (NSABP) study were recently published in the New England Journal of Medicine. This clinical trial, which was begun in 1976, analyzed treatment results in 1,843 patients.

As a result of this study and previous work by NSABP, there has been a dramatic national trend away from the mutilating, debilitating Halsted radical mastectomy that was standard treatment for almost a century, toward more modified, and eventually breast-saving surgical techniques. Radical mastectomy has declined progressively from nearly 50 percent of women treated in 1972 to three percent of women treated in 1981. Data from NCI's Surveillance, Epidemiology, and End Result (SEER) program indicate

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that only one percent of breast cancer patients were treated by radical mastectomy in 1983. Clearly, national patterns of medical practice have been appropriately influenced by the results of this clinical trial.

ACCOMPLISHMENTS

Question: What are some of the more significant accomplishments of the cancer program over the past year?

Answer: Researchers have attained an understanding of the cancer process which has enabled them to create a blueprint of its operation. This past year, we could say that our new understanding of the cancer process offers a paradigm change in cancer etiology, diagnosis, treatment and prevention -- our ultimate goal. Never before has the pace of progress in cancer research been so rapid.

This past year's annual update from the National Cancer Institute (NCI) on survival statistics for cancer patients showed that improvement continues, with the five-year relative survival rate reaching 49 percent for patients diagnosed with cancer between 1976 and 1981. These statistics indicated that over 50 percent of patients diagnosed with cancer are potentially curable. The increases in survival rates were statistically significant for cancers of the colon/lung, prostate, and testis, and for melanoma and Hodgkin's disease. The data are from NCI's Surveillance, Epidemiology, and End Results (SEER) program which monitors the incidence of cancer and the survival of patients in the United States.

Particularly noteworthy among the childhood cancers was the survival rate for acute lymphocytic leukemia, the leading childhood cancer, which continued to show rapid improvement. The five-year relative survival rate was 65 percent for white children diagnosed between 1973 and 1975. During the 1950s, survival from this disease was less than one percent.

SEER data also indicated that survival rates for blacks continue to lag behind those for whites. NCI has major programs under way to define and meet the needs of black patients with cancer.

A new reference on trends for cancer deaths by country published last year, showed that overall cancer death rates would have declined over the years 1950 to 1979 for most of the male population of the United States, if it were not for increases in lung and other smoking-related cancers. Overall rates for females decreased in spite of a large increase in lung cancer, because of decreasing death rates for other types of cancer. The data appear in U.S. Cancer Mortality Rates and Trends: 1950-1979, published by the Environmental Protection Agency in collaboration with NCI.

Specific accomplishments by area of research for the past year include:

CAUSE AND PREVENTION

- A major achievement last year was the discovery by NCI

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scientists that HTLV III, one of the family of human viruses known as Human T-cell Leukemia/Lymphotrophic Virus, is the cause of AIDS. Diagnostic tests to identify the presence of the virus have been developed to protect the Nation's blood supply, and research is under way at NCI's Frederick Cancer Research Facility to develop a vaccine.

- Research on Human T-cell Leukemia/Lymphotrophic Viruses (HTLV) has stimulated renewed interest in the field of human cancer viruses. For example, because of new technology, recent studies indicated that some strains of papillomaviruses, which also cause human warts, are the likely cause of cervical cancer, not herpes virus II as one thought.

- This past year, scientists discovered the structure of the T-cell receptor -- the structure on the surface of "T lymphocytes" by which these cells recognize a substance foreign to the body and stimulate the immune system against it. Understanding the T-cell receptor will help researchers to explain why cancer patients fail to have an effective immune response against cancer.

- NCI scientists determined, for the first time, the function of a normal human oncogene. Oncogenes are small pieces of genetic material in the cells of all individuals. They normally do not cause tumors, but if activated by chemicals, radiation, or perhaps viruses, they may begin some abnormal production of protein and thereby cause the cells to become cancerous. The NCI scientists found that the product of the normal human oncogene, c-sis, one of about 24 such genes identified to date, probably has a role in wound healing. C-sis directs the cell to produce one part of the normal human wound-healing protein known as platelet-derived growth factor, or PDGF. Other recent advances in research have now shown that a number of oncogene products are related to growth factors and growth factor receptors. Such knowledge is the key to developing effective methods to interfere with the cancer process. Intense research has continued to characterize oncogenes and their protein products.

- Most cancers have now been identified to have a chromosomal abnormality. (Genes are located on chromosomes.) Chromosome breakages that allow an oncogene to be relocated and "switch on" have been associated with human lymphomas and leukemias. Now, laboratory methods have been developed to detect "fragile sites" on chromosomes that may indicate increased susceptibility to breakage and rearrangement of key genes. NCI-supported researchers reported this past year the discovery of 51 fragile sites on human chromosomes. This important research may lead to methods for identifying individuals at high risk for cancer, so that by changes in lifestyle or other interventions, cancer might be prevented.

- This past year, NCI supported 26 clinical trials -- the largest number to date -- in chemoprevention. These studies involve chemopreventive agents or dietary factors believed to interfere with cancer progression in people with precancerous

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conditions, or at high risk for certain cancers. For example, folic acid is being studied in women at increased risk for breast cancer in an effort to prevent it. Chemoprevention research continues to identify chemicals and other agents capable of preventing or reversing the process of cancer; and nutrition research seeks to identify foods and dietary habits that may either induce, promote or inhibit cancer.

- The recently identified potent colon mutagen, fecapentaene, found in humans at high risk for colon cancer, was synthesized to provide sufficient material to test its role in the development of colon cancer. Precursors involved in formation of this substance as well as ways to inhibit its formation can now be explored.

- A major prevention awareness program designed to inform the general public about cancer risks and what individuals can do to lower personal cancer risk was launched by NCI last year. This project involves private and public sector organizations which help NCI reach its target audiences of high-risk individuals. In this first year of the program, more than 1.5 million publications were distributed on prevention, and the number of public inquiries on prevention grew from 200 a month to more than 10,000 a month. The focus of the prevention awareness program is on dietary modifications, particularly the increase of fiber and decrease dietary modifications, particularly the increase of fiber and decrease of fat in the diet, and smoking cessation in efforts to reduce the incidence of several major cancers. Last year, NCI developed and promoted smoking cessation materials for use by physicians, dentists and pharmacists with their smoking patients. More than 150,000 kits -- each with enough material for 50 patients — have been distributed.

- The number of calls received annually on the toll-free watts line (1-800-4-CANCER) of the Cancer Communications Network grew to nearly 400,000. This network, based in regional offices in 21 cancer centers provides accurate, up-to-date information on cancer cause, prevention, detection, diagnosis, treatment, rehabilitation, as well as local and national services available to cancer patients. The prevention awareness program doubled the number of inquiries to the 800 line.

DIAGNOSIS AND TREATMENT

Recombinant DNA techniques and monoclonal antibody technologies that have contributed so much to discovering the blueprint of cancer, now hold enormous promise for rapidly diagnosing and characterizing tumors and for treating patients. Specific DNA "probes" have been used to identify genetic alterations in tumor tissue. The presence of oncogenes can be detected and the amount of their gene products measured. At the same time, sophisticated computerized programs for cell image analysis have been used to study isolated cancer cells, and these analyses are being automated for more rapid diagnosis.

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- Monoclonal antibodies, designed specifically to home in on cancer cells, have been applied directly to biopsy samples to aid in tumor characterization and have also been used to detect metastatic breast cancer cells in the body fluids of some patients. These antibodies, which can be tagged with radioactive tracers, have also shown promise in clinical studies to detect extent of disease (including hidden metastasis) in patients with colon and other cancers. Monoclonals have already helped to distinguish one type of lymphoma from another. It is important to diagnose cancer early and accurately so the best treatment can be chosen.

- Monoclonal antibodies have proved to be valuable tools, not only to diagnose and classify cancers, but also to classify subsets of cells of the immune system. The availability of these antibodies quickly provided a valuable test for the detection of the major immunologic defect in AIDS, i.e., the profoundly suppressed ratio of helper-to-suppressor T cells. Monoclonal antibodies were used this past year to eliminate T-cell subsets which are responsible for graft-versus-host disease that may threaten bone marrow transplantation. New technology with use of monoclonal antibodies has increased the possibilities of organ and bone marrow transplantation as treatments for cancer (particularly lymphomas and leukemias). Reports of research last year indicated successful bone marrow transplantation could allow patients to survive very high doses of chemotherapy used to destroy tumor.

- Two new markers to detect prostate cancer have been discovered this past year and will be studied further. The availability of a sensitive, specific screening method for prostate cancer could lead to earlier diagnosis and increased curability of this disease.

- A monoclonal antibody was designed last year to detect a new marker found in the blood of patients with ovarian cancer.

- Major advances in laboratory research have included the establishment of human lung cancer cell lines. This has enabled researchers to work with tumor "markers" and monoclonal antibodies to type lung cancer cells, determine some of their growth factor requirements, identify certain oncogenes in some of these cancers and begin testing the sensitivity of growth factors, such as bombesin, a small protein which stimulates the growth of lung cancer cells, has led to the recent development of antibodies which neutralize bombesin and prevent the growth of lung tumors in mice. Now, clinical trials of antibombesin antibodies are planned.

- Since most cancer patients die from metastasis, it is essential to understand and then block the way cancer cells metastasize. In the cancer process, cancer cells can travel from the primary cancer through the bloodstream, developing secondary deposits in other parts of the body. Such metastatic cancer cells invade and crowd out normal tissues in vital organs such as the brain, liver and lungs, and are the major cause of death from cancer. Researchers have discovered important biochemical mechanisms involved in the

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metastatic process. This past year, they have identified specific genes associated with this process, by identifying differences between the genes of cancer cells that do spread and those that do not. For the first time, we have a model system and thus a scientific handle to study ways of interfering with deadly metastases. In experimental animal systems, scientists have been able to inhibit the receptors of the protein laminin used by cancer cells to stick to membranes as they prepare to spread, thereby preventing cancer cells from invading other tissues.

This year we can say that opportunities lie before us to block cancer cell transformation and growth, and invasion and metastasis, the entire spectrum of the cancer process.

- Collaboration between surgery, radiation therapy, chemotherapy and therapy with biological response modifiers continued to improve the outlook for cancer patients in the past year:

  - Combination therapy has allowed trends towards less radical surgery, supplemented by chemotherapy and radiotherapy, for patients with breast, rectal, prostate cancers, and extremity sarcomas. In fact, segmental mastectomy with radiation for early-stage breast cancer now appears to be equivalent treatment to modified radical mastectomy at a projected survival rate of five years. In another type of cancer, a consensus development conference concluded that limb-sparing treatment was feasible and appropriate for a significant proportion of patients with life-threatening or potentially disabling extremity sarcomas.

  - Chemotherapy has, for the first time, demonstrated new success in hard-to-treat tumors, like lung cancer and (combined with radiotherapy) pancreatic cancer.

  - Surgery has now been used in a new way to successfully remove lung and liver metastases and to cure some patients with advanced colon cancer and sarcomas.

  - Promising results have also been seen in early studies from use of monoclonal antibodies to treat pancreatic cancer.

  - An exciting development has occurred in breast cancer. This past year, a review of (early-stage) breast cancer studies worldwide clearly showed that chemotherapy and hormonal therapy substantially decrease mortality. Early treatment with chemotherapy also saw success in lung, rectal, head and neck cancers, and childhood sarcomas.

  - In the development of anticancer drugs, NCI began a new approach to the screening of new anticancer -- testing candidate drugs directly against human tumor cells which can now be grown in reproducible fashion in the laboratory. It is expected that this method of selection will allow greater success in discovering

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effective drugs than the standard systems which use animal (usually mouse) tumors.

- Progress continued in understanding and planning therapy to "outsmart" certain metastatic cancer cells that become "intuitively" drug resistant. Researchers have found ways to overcome drug resistance in cells grown in the laboratory. For example, a class of drugs called calcium channel blockers, commonly used to treat heart problems, appears to overcome a mechanism involved in drug resistance. Use of several of these approaches was started this past year in clinical trials.

- Studies of biological agents, such as Interleukin-2 (IL-2), interferon, and monoclonal antibodies provided promising early results in cancer treatment. Immune cells activated in the laboratory by IL-2 seek out and destroy tumor cells and have cured metastatic tumors in mice. These so-called lymphokine activated killer cells (LAK) were started in clinical trials last year at NCI. Alpha interferon has been most effective against hairy-cell leukemia. This agent was also active against renal cell and ovarian caners and lymphomas. Monoclonal antibodies moved ahead in clinical trials this past year in pancreatic, lung and lymphoid cancers.

- Newly available hormonal agents became available for clinical studies in treatment of metastatic prostate cancer in a large intergroup study.

- In the past year, NCI examined patient samples of an unproven cancer treatment called Immunoaugmentative Therapy (IAT) and found that treatment samples were contaminated by bacteria and were positive for hepatitis B surface antigen and/or anticore antibody. NCI advised physicians that the efficacy of this treatment remains unproven and that the risk of receiving contaminated blood products may be considerable. NCI alerted the medical community, and worked through the media to alert the public about this health risk.

- To foster information transfer from basic research to the patient's bedside, NCI continued to support and strengthen a network that links basic science laboratories, cancer centers, cooperative groups of clinical researchers, community oncologists, and practicing physicians. Last year, research studies were made available to cancer patients in nearly 900 community hospitals nationwide in addition to cancer centers and universities.

  NCI developed PDQ (Physician Data Query) to speed the dissemination of research findings to the medical community. This computerized database provides physicians with the latest and best treatment information for their cancer patients. Last year the system became widely accessible. By encouraging the practice of up-to-date cancer treatment nationwide, PDQ is expected to contribute significantly to the NCI goals for by year 2000: to reduce the Nation's mortality rate by 50 percent through better screening,

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diagnosis, treatment, and prevention of cancer.

CANCER CONTROL

Question: I understand that the Cancer Control program is working with state and local governments in an attempt to develop cancer control programs at that level.

How do these control programs work?

Answer: NCI's most recent initiatives to support health agencies have developed along several lines:

- Technical Assistance to respond to scientific requests for technical advice through phone/letter response, on-site visits, and by a arranging for technical experts to provide direct consultation.

- Capacity Building to enhance the technical capability within health agencies to plan, develop, and evaluate cancer control efforts. This initiative is being developed through a model program of cooperative agreements to be supported by the cancer control program.

- Guidelines and Protocols which will provide step-by-step plans for implementing cancer control measures based on the latest scientific results for those key areas that contribute most to achieving the year 2000 objectives.

- Analytic Services to assist health agencies in effectively utilizing existing mortality and other cancer data to prioritize, plan, and/or evaluate intervention programs.

- Liaison and Information Exchange to foster greater interaction between NCI and health departments as well as among health departments to share information on implementation strategies and their successes and failures.

Question: How are the States made aware of this resource?

Answer: Up to this point, interactions with state personnel have occurred in two primary ways:

- Reaction to requests for technical assistance.

- Input from two meetings of a working group that is advising us on the development of this program. The working group consists of four state health officers, three city/county health officers, three state-level cancer control program directors, one representative from the Association of State and Territorial Health Officials, and several representatives of other interested federal agencies.

Through these two mechanisms, in 1984 we interacted with representatives of 23 states and nine local health agencies. A major objective for 1985 is to improve our liaison contact with health agencies.

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We plan to proactively offer specific technical assistance after the guidelines/protocols and the year 2000 implementation strategies are finalized. We have developed a mailing list of cancer control contacts in state health departments and will utilize it to announce the availability of the technical development cooperative agreement when it is formally available. Additionally, we are planning a national conference in early 1986 to present our year 2000 objectives and rationale and to discuss implementation strategies with health department personnel.

Question: How does the funding mechanism work in state programs -- are there any state funds required?

Answer: The proposed cooperative agreement for technical development in health agencies is designed to increase the capacity and capability of health departments to conduct intervention programs utilizing local funds. NCI will cover the costs of accessing and developing technical expertise, developing analytical bases, organizing coalitions of community groups to plan and prioritize programs, and, finally, conducting evaluation research to demonstrate the effectiveness of cancer prevention and control efforts. Health departments will be required to demonstrate a commitment to provide the resources to implement the intervention programs. This project is a model demonstration program with up to five jurisdictions to be funded at the outset.

CANCER PREVENTION

Question: Diet and nutrition have become a part of the cancer prevention lexicon.

I saw that you recently endorsed an ad by Kellogg's that indicates that fiber in the diet may help in preventing cancer.

How much more are you collaborating with industry in this regard?

Answer: The National Cancer Institute is not endorsing an ad by Kellogg's, but rather is allowing the Company to include the Institute's basic diet messages in its ads for All-Bran and on the back panels of six of the bran cereals manufactured by the Company.

A number of other companies have expressed an interest in cooperating with NCI in the same way that Kellogg's has, and the Institute has been willing to consider such a venture with any company which markets a food product that fits within the NCI dietary guidelines. The Institute announced early that it was not working exclusively with the Kellogg Company. None of the other companies, as far as NCI knows, has proceeded beyond the fact-finding stage where they obtain information about NCI's diet recommendations and the scientific support for them.

NCI believes that this kind of collaboration with industry can benefit the public health because the private sector can extend greatly the exposure of the diet messages to the public. However, before any further collaboration can take place, the Institute would need to be assured that such collaboration would fit within the Food and Drug Administration's policies on food labeling. It

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appears that FDA thinks it desirable to allow responsible marketers to provide useful health advice to the public, but hopes to find a way to do this while preventing manufacturers of fraudulent products from doing the same thing. NCI supports this view.

RESEARCH FUNDING PRIORITIES

Question: We have received occasional letters that have expressed concern about funding priorities at the various institutes.

What factors are taken into account when decisions are made as to which approved proposals are funded?

Answer: In addition to the priority score (the Initial Review Group's rating of technical merit reflecting the quality of the proposed research, its biomedical significance, the probability of success, the experience and qualifications of the investigators, and the adequacy of the needed resources and facilities) other critical factors in any funding decision are: the relevance of the research in the context of the particular program area of NCI, and any overlap with ongoing research being supported through another grant, or another mechanism.

Question: Do the study sections weigh the potential success of research as a major factor in making their judgments?

Answer: Yes. A specifically stated criterion used in review committees is the probable success of the research effort. This becomes an element in the assessment of the investigators as well, in that the reviewers look at the history of success (or lack of success) of the principal investigator in his/her previous ventures. Although the high-risk approach to a conventionally intractable problem is often felt to fare poorly in NIH Study Sections, innovation need not be equated to poor probability of success. By and large, the potential for success, as perceived by most Study Sections, is inferred from a) the principal investigator's clear, well-rationalized experimental paradigm, b) the methods chosen, and presented, for demonstration of an hypothesis, and c) the intrinsic value to biomedical research of the information to be gained in the course of the project.

Question: Do you feel that basic research proposals are being nosed out by proposals which are likely to have more immediate application?

Answer: No. In fact, clinical research supported, through investigator-initiated grants do not fare as well in review as basic research proposals. The same is true of proposals for nutrition research.

Question: If this is true, are we losing out on innovative or creative research?

Answer: While this does not appear to be the case, the NCI is sensitive to the concern and makes every effort to identify and support high-quality innovative research. Recently, NCI initiated a new grant mechanism — the Outstanding Investigator Grant

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(OIG) -- where the technical evaluation is made strictly according to the accomplishments of the principal investigator rather than on a specific research proposal. The OIG will allow the grantee freedom for maximum creativity and innovation.

ADVISORY COUNCIL'S ROLE IN RESEARCH

Question: What role does the National Cancer Institute's Advisory Council play in the prioritization of research?

Answer: The National Cancer Advisory Board performs an important advisory function in the prioritization of NCI's research programs. It influences program priorities in three major ways:

- It is the legally constituted body that performs the second phase of the review of research grant applications (the first phase is performed by the Initial Review Groups) and recommends approval or disapproval to the Director, NCI. The NCAB may concur with the priorities recommended by the Initial Review Groups or disagree with a recommended action on a single grant and can change the proposed action. It can also recommend specific applications for exceptional pay consideration on the basis of perceived high-program relevance or of specific promise. The Board advises the Director, NCI, regarding its assessment of needs for special initiatives to exploit new and exciting research findings. The lay members often convey their sense of needs of the public good in the direction of NCI's research programs.

- The annual November NCAB Program Review meeting is devoted to a summary of all scientific activities and business transactions by NCI operating Divisions. This is done by the Division Directors and their BSC Chairmen from the standpoint of scientific program priorities and budgetary requirements established from deliberations of the respective divisional boards with Institute management staff. Another important aspect of the annual review meeting involves the selected presentations by scientists working in extramural or intramural laboratories, or both, and clinical investigators of the achievements of certain scientific programs having a potentially highly significant impact upon solving the cancer problem. Also included is a discussion of particularly promising opportunities and leads which should be pursued.

- Through its several subcommittees, the NCAB can also provide the Director with its recommendations on specific programs and program priorities throughout the year. Since 1980, the Director has asked the NCAB to participate directly in the establishment of program priorities under various budget situations. This participation has been accomplished by detailed program and budget discussions by the Subcommittee on Planning and Budget and by the entire Board.

In addition to the NCAB, each of the Board of Scientific Counselors (BSC) meet at least three times a year to review divisional intramural and extramural programs and budgets and to provide each Division Director advice and recommendations on program content and priorities. Each BSC consists of between 15 to

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20 members selected for high scientific qualifications in areas reflective of the Division's total research program. Although regulations require that the Chairman and at least 75 percent of the members be non-federal employees, in practice this is rarely true. Currently, all members of four BSC are non-federal employees. In addition to providing advice on program priorities and budget, the BSC also review requests for new contracts and contract recompetitions, provide advice to the Division Director on unusual management issues, and perform the peer-review of intramural research.

Question: Does the Council have a policy toward funding of research out of priority order?

Answer: Institute program staff develops its funding plan subsequent to the National Cancer Advisory Board concurrence with study section approved applications. The NCAB considers recommendations from program staff for funding particular grant applications out of priority sequence and when convinced of the need, supports such recommendations. The Board also considers applicants rebuttals of review reports and sometimes recommends payment out of priority sequence. The NCAB is informed of, and provided annually with the justification for, all funding plan exceptions.

Question: How is research priority decided upon within the Institute?

Answer: Within the NCI, there are several sources from which advice on priority setting and program selection is sought. The Congress helps determine priorities through appropriations and oversight hearings; special studies such as by GAO and Office of Technology Assessment; and legislative mandates or directives resulting from these hearings or studies. The Department of Health and Human Services, including the Public Health Service, provide priority guidance through budget reviews, and the necessity to meet certain national priorities on a cross-agency cooperative basis. The National Institutes of Health establishes certain priorities through the budget review process. The President's Cancer Panel helps to gather views from the scientific community through the panel meetings, and reports to the President any matters that might impede the progress of the National Cancer Program. The National Cancer Advisory Board provides overall advice and guidance to the Director, NCI and helps set priorities in three major ways, including: their legally constituted role as the second phase of peer review of research grants; the annual NCAB program review with the Institute's operating divisions and the strong participation of the Chairman of the Board of Scientific Counselors (BSC) for each of the divisions; and the NCAB subcommittees, including the Subcommittee on Planning and Budget, that make recommendations on specific programs and program priorities throughout the year. The BSC's for each of the four operating divisions meet at least three times a year and play an important role in priority setting in the following areas: provide concept review of extramural programs during the three regularly scheduled meetings; conduct peer review of intramural research with each laboratory being reviewed every three to four years; provide assistance to the division director on major scientific and operating issues; and each division conducts a

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program budget review with their BSC each fall. The NCI Executive Committee meets each week to decide on Institute-wide policy and operating issues, including grants funding issues. Finally, the NIH and NCI initial review groups that review research grant applications provide relative priorities and have been a critical factor in the development and maintenance of the highest quality research.

The NCI planning and budgeting process provides for a systematic and sequential interaction of these groups with NCI in order to meet the goals and objectives of the National Cancer Program. Twice each year the Institute holds a Director's Meeting that involves the NCI Executive Committee and key administrative personnel in order to identify priorities, areas of high scientific promise, and to establish operating policies for the upcoming fiscal year. In January, the meeting primarily concerns overall budget policy, the identification of major areas of scientific emphasis, and a review of the current year's operating plans. In July, the meeting is primarily concerned with specific operating/budget levels for each division for the upcoming fiscal year consonant with the priorities and goals previously identified. These plans are reviewed by the BSC's in September and by the NCAB at the November program review. Each spring the NCI Executive Committee and the NCAB subcommittee on planning and budget meet to establish the policy parameters for the development of the preliminary budget, including the NCI By-Pass Budget to OMB, for two fiscal years hence. The preliminary budget, including program plans and priorities, are reviewed by the full NCAB in the early fall.

In summary, program priorities in terms of budget and operating plans are the result of interaction between corporate management represented by the Director, NCI and the NCI Executive Committee, and the advisory function represented by the NCAB and the BSC's for each of the four operating divisions. The entire review function for grants and contracts is brought together by the Division of Extramural Activities, NCI. The President's Cancer Panel provides a general oversight for the National Cancer Program. The Director, NCI bears the responsibility for setting priorities in terms of both implementing new programs and modifying or terminating ongoing programs. He basis these decisions on extensive consultation with groups of scientists and administrators, both internal and external, and on direction received by higher organizational levels within the executive branch, and by Congress.

Question: Is there a correlation between the areas of expertise of the members of the Advisory Council and the Cancer Institute's priority areas?

Answer: The representative of scientific and clinical expertise on the NCAB is designed to be reflective of the breadth of the cancer research community. The Cancer Act of 1971, and its subsequent amendments, specifically require that the expertise of the Board include both scientists and lay members and that a designated number of the professional members possess expertise in environmental carcinogenesis or experience in the treatment of cancer patients. Within those requirements, the process attempts

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to assure that nomination slates reflect changing NCI emphasis as mandated by state-of-the-art in basic oncology research as well as high-priority areas in cancer medicine.

EVALUATION OF INTRAMURAL PROGRAM

Question: What internal evaluation and quality control mechanisms are currently in place to oversee NCI's intramural program?

Answer: The intramural programs in each of our four operating research divisions are qualitatively and quantitatively evaluated primarily by the division's Board of Scientific Counselors, a group of non-government advisors who review the research and make critical peer judgments. These divisional Boards conduct regularly scheduled site visits to each intramural laboratory or branch every three to four years. During these site visits each project, the work of each NCI investigator, and the direction of the laboratory as a whole is critically examined. Since the reviewers are provided beforehand with complete detail on resource, scientific activities, professional background of personnel, and the like, their formal, post-visit report to the responsible Division Director includes recommendations on a wide spectrum of matters including shifts of financial and personnel resources, changes in research emphasis, and on occasion, even organizational changes that the Board feels will benefit the conduct of the research involved.

In addition to these site visits, the Boards meet in general session several times each year to: 1) advise divisional officials on overall intramural research activities, 2) review and conceptually critique the division's proposed investments in grant and contract funded research; 3) examine and comment upon the entire divisional budget; and 4) provide advice on any special problems the division is facing. Thus, the Institute's technical conduct of internal research activities, as well as its management of them, is comprehensively scrutinized and very much shaped by top experts in the outside scientific community; and their input affects everything from the work of individual scientists to the operation of multifaceted programs that constitute major segments of the Institute's total activities.

Question: How does the review of intramural laboratories compare to the peer review of extramural grants?

Answer: The two processes are quite comparable. The intramural site visit process described above was deliberately modeled, to the maximum extent practicable, after the extramural grant peer-review process.

CANCER SURVIVAL RATES

Question: What is NCI's response to charges that cancer survival rates have not improved much in recent years, that gains made in the 1960's were greater than in the last decade?

Answer: Clear gains in cancer patient survival have been made since the 1960s, and the cancer sites showing the greatest

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increases are evident. To cite just a few examples, five-year relative survival for Hodgkin's disease has increased from 40 to over 74 percent over the span from 1960 to 1980; during the same period, testicular cancer survival improved from 63 to 87 percent; prostate 50 to 71 percent; indeed, cancer survival overall has increased from 38 to 49 percent.

The relative rate of progress during the 1960s compared with the 1970s can be addressed by calculating the average annual percent changes in relative survival rates. Data collected in the End Results Study during the periods of 1960 to 1963 and 1970 to 1973, and continuously and consistently by the SEER program from 1973 to the present, allow us to calculate and compare average annual changes in survival rates for the two decades.

As shown in Table 1, survival of all cancer sites combined for patients diagnosed in the 1960s improved at approximately the same rate as survival for patients diagnosed in the 1970s, rising at about one percent per year from the early 1960s to the end of the last decade. Of particular interest is the survival improved more for blacks than whites in the 1960s (1.5 percent versus 1.0 percent per year) and was slightly better in the 1970s (0.9 percent versus 0.7 percent per year). Over these two decades, black cancer survival rose from 27 to 38 percent.

Survival for children with cancer has shown great improvement over both decades, although the rate of increase was greatest in the 1960s. During that decade, there was a six percent increase in survival each year compared to only a four percent increase each year in the 1970s. (In 1960, cancer survival for children was 28 percent; recent data for patients diagnosed between 1976 and 1981 show a 60 percent survival rate.) The rates of increase differ, as expected, by cancer site within the broad category of children's cancer. Large improvements in survival for children with acute lymphocytic leukemia and Wilm's tumor occurred in the 1960s, while the average annual gain in neuroblastoma has been higher in the 1970s.

Most adult tumors, on the other hand, (Table 2) have shown more improvement in survival over the 1970s than in the 1960s. These improvements have occurred for cancers of the esophagus, stomach, colon, lung, melanoma, prostate, and testes. Hodgkin's disease, rectum and non-Hodgkin's lymphomas still show an improvement of 1.4 percent annually in the 1960s, but in the 1970s there was nearly a five percent increase for each year in the five-year relative survival rate.

It cannot be expected that research will progress at the same rate for all cancer sites. Yet, the overall upward trend in survival has been smooth and nearly the same for two decades. The result is continuously improving prospects for the Nation's cancer patients.

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Table 1

ALL SITES COMBINED

FIVE-YEAR RELATIVE SURVIVAL RATES
AND AVERAGE ANNUAL PERCENT CHANGE IN SURVIVAL

	YEAR OF DIAGNOSIS 1/		A.A.P.C. 1960-63	YEAR OF DIAGNOSIS 2/		A.A.P.C. 1973-75
	1960/ 1963	1970/ 1973	TO 1970-73	1973/ 1975	1976/ 1981	TO 1976-81
RATES/SEX						
ALL RACES, BOTH SEXES	38	42	1.1%	48	49	0.7%
WHITES, BOTH SEXES	39	43	1.0	49	50	0.7
BLACKS, BOTH SEXES	27	31	1.5	37	38	0.9
WHITES, CHILDREN	28	45	6.1	53	60	4.4

1/ Rates are based on unpublished end results group data from a series of hospital registries and one population-based registry.

2/ Rates are from the SEER program. They are based on data from population-based registries in Connecticut, New Mexico, Utah, Iowa, Hawaii, Atlanta, Detroit, Seattle-Puget Sound and San Francisco-Oakland. Rates are based on follow-up of patients through 1982.

A.A.P.C. - Average Annual Percent Change

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Table 2

FIVE-YEAR RELATIVE SURVIVAL RATES
AND AVERAGE ANNUAL PERCENT CHANGE IN SURVIVAL
FOR SELECTED SITES FOR WHITE CANCER PATIENTS

	1960/ 1963 1/	1970/ 1973 1/	A.A.P.C. 1960-63 TO 1970-73	1973/ 1975 2/	1976/ 1981 2/	A.A.P.C. 1973-75 TO 1976-81
ESOPHAGUS	4	4	0.0%	5	6	6.7%
STOMACH	11	13	1.8	14	15	2.4
COLON	43	49	1.4	49	53	2.7
RECTUM	38	45	1.8	47	49	1.4
LUNG	8	10	2.5	12	13	2.8
MELANOMA OF THE SKIN	60	68	1.2	76	80	1.8
BREAST (FEMALES)	63	68	0.8	74	75	0.5
CERVIX UTERI	58	64	1.0	68	67	-0.5
ENDOMETRIUM (CORPUS UT.)	73	81	1.1	89	86	-1.1
OVARY	32	36	1.3	36	37	0.9
PROSTATE GLAND	50	63	2.6	65	71	3.1
TESTIS	63	72	1.4	76	87	4.8
BLADDER	53	61	1.5	73	74	0.5
HODGKIN'S DISEASE	40	67	6.8	67	74	3.5
NON-HODGKIN'S LYMPHOMA	31	41	3.2	45	48	2.2
LEUKEMIA	14	22	5.7	33	33	0.0

1/ Rates are based on data from a series of hospital registries and one population-based registry. They are summarized in Cancer Patient Survival Experience.

2/ Rates are from the SEER program. They are based on data from population-based registries in Connecticut, New Mexico, Utah, Iowa, Hawaii, Atlanta, Detroit, Seattle-Puget Sound and San Francisco-Oakland. Rates are based on follow-up of patients through 1982.

A.A.P.C. - Average Annual Percent Change

Question: Should NCI change its focus from treatment to prevention of cancer?

Answer: During the past several years, the NCI has made a major shift in the appropriate balance of treatment and prevention research. Both areas need vigorous support. With respect to prevention research, as a result of exciting new scientific discoveries and technological advances, unique opportunities are available to interfere with cancer once it has occurred, and even to inhibit its occurence altogether. These same achievements have also enabled the development of new treatments which promise to be extremely effective with very few negative side effects.

We are at a unique point in understanding the cancerous

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process — we now believe that all the abnormal aspects of malignancy parallel a normal process essential to our earliest development. During embryonic growth, there is necessary unrestricted growth of cells, but this is shut down when equilibrium is reached. It is increasingly clear that cancer represents a loss of the regulation of cell growth. In the cancer process, a group of recently discovered genes, called oncogenes, appear to be "switched on" again after embryonic development, resulting in the wild growth that is cancer. This knowledge has armed us with the opportunity to be able to block cell transformation and growth by possibly blocking the function of oncogenes.

The second major aspect of the malignant process which appears to have been a normal embryonic function is cell migration and invasion of other vital organs and tissues. This is called metastasis and is the primary cause of death from cancer. Recently, researchers discovered important biochemical mechanisms involved in the metastatic process, and have identified specific genes associated with this process. For the first time, we have a model system and a good basis for studying ways to block metastasis and invasion. In experimental systems, in fact, scientists have been able to inhibit the receptors of the protein laminin used by cancer cells to stick to membranes as they prepare to migrate, thereby preventing cancer cells from invading other tissues.

This new understanding of the cancer process certainly offers a paradigm change in approaching cancer etiology, diagnosis, treatment and prevention, and diagnosis methods and techniques in order to save lives.

NCI, then, ultimately strives to prevent cancer. Barring that, however, we now have a unique opportunity to interfere with the further development and spread of an established malignancy by application of state-of-the-art treatment and diagnostic techniques. NCI is committed to reduce cancer mortality in the U.S. by 50 percent of current rates by the year 2000. An important component of this goal is prevention, based on sound information and knowledge generated through NCI support during the last 15 years. The achievement of this national goal, however, will also require aggressive and broad-based application of state-of-the-art methods of screening, detection and treatment.

PREVENTIVE RESEARCH

Question: In a speech before the American Pharmaceutical Association Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research.

What types of preventive research are being done by your institute?

Answer: The National Cancer Institute is supporting a spectrum of preventive research, including both primary and secondary prevention. Primary prevention includes research aimed at preventing the initiation of disease, while secondary prevention means detecting a disease early so that it can be treated and cured before it has caused morbidity.

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In primary prevention NCI is supporting research on smoking, diet, chemoprevention, occupation, radiation, viruses, and environmental risk factors. In each of these scientific areas the research activities may be classified into three broad categories including laboratory research, epidemiologic research, and human intervention research.

Laboratory research on agents that can inhibit, reverse or delay the development of cancer. Such agents can derive from naturally occurring products such as human foods, from chemical synthesis, or from various biological sources. The research includes studies on experimental inhibition of carcinogenesis, inhibition or suppression of malignant transformation in culture, mechanisms of action and metabolism of preventive agents, synthesis of chemopreventive compounds, structure-function relationships, and pharmacologic disposition.

Currently, emphasis is being placed on natural sources of inhibitors of carcinogenesis such as human foods. These studies are directed at the isolation and identification of inhibiting substances and determination of their anticarcinogenic properties and mechanism of action in animal models and tissue cultures. Other research includes studies of inhibition of tumor development in liver, lung, digestive tract and mammary gland by antioxidants, and inhibition of tumors of breast and urinary bladder by retinoids (Retinoids are synthetic analogues of natural vitamin A). In addition, the NCI supports the synthesis of new retinoids and their testing as cancer preventive agents, and the synthesis of large amounts of radiolabeled retinoids for metabolic and pharmacologic investigations.

Leads from laboratory research and epidemiologic research form the basis for formulation of human intervention research. An example is research on diet and cancer prevention. Epidemiologic research suggests that the amount of fat in the diet correlates with the risk of developing several types of cancer, including breast cancer. In animal research, the incidence of breast cancer is strongly influenced by dietary fat. NCI is now supporting a clinical trial of a low fat (20 percent of calories as fat) diet in women who are at high risk for breast cancer. The intent is to reduce the incidence of breast cancer. This would confirm the epidemiologic observations and would document that the observations in animals are relevant to humans. This trial will also enhance our understanding of how changes in diet can be enhanced and encouraged.

In secondary prevention, research is ongoing on earlier detection of cancer of the breast, cervix, lung, colon, and rectum. In one study, detection of colon cancer by testing for occult blood in the stool has shown a reduction in mortality from colon cancer. In other research, the method for measuring occult blood in the stool has been significantly improved. The challenge now will be to encourage wider utilization of fecal occult blood testing, and NCI is supporting research on this as well. Wider utilization of cancer detection strategies could significantly reduce cancer mortality.

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Question: What percent of your budget is directed to preventive research?

Answer: 28.6 percent of the NCI budget was directed to prevention research in FY 1984. Approximately, 28.2 percent and 28.3 percent of the NCI budget is estimated for prevention research in FY 1985 and FY 1986, respectively.

Question: How are the results of this research being translated into useful public information?

Answer: For the past year, the Institute has been conducting major Cancer Prevention Awareness Program. The emphasis has been on a mass media approach to let Americans know that not everything causes cancer and that there are steps every American can take to reduce personal risk of cancer. Surveys conducted before the Campaign began showed that the majority of Americans believed incorrectly that everything causes cancer and there was nothing they could do personally to reduce risk.

The second phase of the Campaign, beginning this year, will feature public education program aimed at high-risk groups. For example, in May NCI will begin a media program aimed specifically at black audiences. Other programs are being developed to meet the needs particular localities and regions around the United States. A number of other organizations already are collaborating with NCI on this phase. They include cancer centers, state health departments, private industries which sponsor employee health programs, church groups, unions, schools, hospitals and other health care delivery organizations, and voluntary health organizations.

The main messages emphasized to date are "no smoking", and that a diet high in fiber and low in fat can help reduce the risk of some kinds of cancer. The Campaign also addresses other risk factors, including: chewing tobacco and snuff; occupational exposures to cancer-causing agents; x-ray exposure; excessive sunlight exposure; and excessive alcohol consumption, especially in combination with smoking.

Still another component of the information dissemination program is the direct response to public inquiries concerning cancer. The Cancer Communications Network supports a nationwide chain of information centers, accessible by a toll-free number, to provide information about cancer and local cancer resources to patients and their relatives. In 1984, the Institute responded to some 115,000 letters and 135,000 telephone inquiries, including 120,000 toll-free calls as part of the National Cancer Information Service System. In addition, in 1984 the Institute distributed 14 million publications of over 300 titles.

Other major components of the information dissemination program, but directed at a professional audience, include the Community Clinical Oncology Program (CCOP) which involves local physicians in clinical trials to expedite the transfer of advances in care; programs for specific cancers such as the Smoking

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Prevention and Cessation Program, the Breast Cancer Education Awareness Program. In addition, NCI publishes two major journals, The Journal of the National Cancer Institute and Cancer Treatment Reports, and operates the International Cancer Research Data Bank, located at the National Library of Medicine. The International Cancer Research Data Bank includes information bases on cancer literature, on cancer projects and on clinical protocols.

In addition, five online databases (CANCERLIT, CANCEREXPRESS, CANCERPROJ, CLINPROT, and PDQ) which comprise the NCI's CANCERLINE System, are distributed through the Medical Literature Analysis and Retrieval System (MEDLARS) of the National Library of Medicine. The CANCERLINE database provides online access to cancer research data to basic scientists, and clinical practitioners at over 3,000 locations within the United States and 12 other countries.

The effectiveness of this comprehensive program depends on each component link remaining strong and in place. Research results must be translated from the research setting to the practice setting in order to be effective. The public must be informed as to ways in which cancer can be prevented, detected early, and treated effectively. In particular, intensive efforts must be made to convince those who smoke or use smokeless tobacco that they have 10 to 20 times the risk of developing cancer and two to three times the risk of heart disease than a non-smoker, and to provide effective ways for these persons to break the habit. And, perhaps most important, today's youngsters must be convinced to not smoke and to not use smokeless tobacco.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: In recent years the requirements for administration and management of extramural programs has increased steadily while at the same time staff has been reduced due to the reduction in federal employment. In order to balance this workload discrepancy, it has been necessary to improve how we do business, and increase efficiency. This is being accomplished in several ways.

Better procurement planning is one of the most important ways to reduce administrative costs and improve efficiency. This has led to earlier decisions on funding and a more evenly distributed workload resulting in a significant decrease in overtime costs. Similarly, equalization of the grant workload reduces backlogs, thus reducing overtime costs and at the same time improving product quality. Related to this is the early receipt of applications and improved budget planning that allows for early funding decisions. Further streamlining of the grant award process is also important. While this has been done to a great extent especially with regard to RFAs and cooperative agreements, we are working with the NIH on still more improvements in order to eliminate duplication and unnecessary administrative review. Finally, we are continuously reviewing personnel needs with the

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goal of improving position management and enhancing organizational efficiency.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: The success of any complex, multifaceted scientific endeavor, such as the NCI depends on proper management and careful disposition of resources. Changes in management of the National Cancer Program affecting this allocation of resources have been a high priority. We have implemented major changes which form the basic framework for ongoing decision making and priority setting within NCI. First, the processes of decision making and priority setting for each NCI division is elevated to public view and conducted with expert advice from four divisional Boards of Scientific Counselors, constituted entirely of highly qualified non-government scientists. Second, decisions based on the advice received from all these advisory bodies are acted on corporately by the NCI Executive Committee, composed of the Institute's Division Directors and Associate Directors each of whom is responsible for a major program segment at NCI. In addition to the weekly meetings of this group, every year two meetings are held with the Executive Committee and other NCI managers/administrators to review Institute operations and plans for the future. In conjunction with discussions of scientific initiatives these meetings also include reviews of management practices that could/should be altered to improve Institute operations. Third, NCI's business management systems were centralized in the Office of the Director. Under the Associate Director for Administrative Management administrative policies are now implemented in a unified fashion. Fourth, the peer review and financial management of grants and contracts have been streamlined. Fifth, the intramural peer-review process was established on an Institute-wide basis. Each intramural laboratory is site-visited periodically by subcommittees of its divisional Board of Scientific Counselors supplemented by additional scientific peers. Before and during these site visits, branch and laboratory chiefs are required to describe their past research and future plans as well as all of the budgets.

This framework represents an ongoing process which contributes to decisions relating to scientific and administrative efficiencies. We do not view the administrative and scientific activities as totally mutually exclusive. Rather, expertise in both areas is essential to overall success. Some more recent examples of implementing administrative procedures which contribute to overall Institute efficiency include: 1) the development and implementation of streamlined review procedures for RFAs and Cooperative Agreements; 2) reorganization of the Grants and Contracts Administration Branches to improve workload distributions and review of operational financial management decisions to improve work flow throughout the year; and 3) establishment of an NCI steering committee to oversee the implementation of our office automation and automated data processing methods.

In addition, the NCI works with the NIH Productivity Review Committee to review and monitor the agency's implementation of A-76, and to carry out associated efficiency and cost studies

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relative to various ongoing activities.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: Improved procurement planning and management of workload has resulted in a significant reduction in overtime costs. This was accomplished even with a decrease in personnel of about 15 percent. Other changes and improvements that have helped improve efficiency include the following:

- Standardization of internal work forms have reduced administrative costs associated with the contracts process.

- Converting official grant files to microfiche has reduced administrative cost and improved the efficiency of grant administration.

- Retraining of technical staff to handle more para-professional duties in the grants and contract award process.

- Improved budgeting for administrative tasks, including special monitoring procedures on the costs for travel and training.

- The application of Automatic Data Processing in the following areas:

  - Electronic Mail System
  - Pre- and Post-Award Tracking Systems for both grants and contracts
  - Computer-generated letter system that allows us to produce 1,200 to 1,400 letters overnight relative to Board Review.
  - An interactive award system that allows computer-produced awards to be prepared directly by the Institute, saving duplication.
  - An automated approval list that eliminates duplicate signatures and hand entries for obligation of award in the accounting system.
  - Implementation of a computerized grant file-folder locator system.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: We are attempting to maintain both the level of effort and the quality of the review process by more efficient management of attendant costs. Among the steps taken to date are:

- Increased office automation procedures.

- Shift in some review responsibilities to parent committees from site visit teams.

- Increased program/review staff surveillance of applications to exclude those of especially poor quality for revision prior to site visit reviews.

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- Consideration of reduction in site visits of revised applications.

- Reorganization of the Grant Review Branch.

CANCER MORTALITY

Question: During our hearings last year, you announced that NCI intends to halve the U.S. age-adjusted cancer mortality by the Year 2000. Do you still feel this is a realistic goal?

Answer: A reduction in the age-adjusted cancer mortality rate by half by the year 2000, although a seemingly ambitious goal, is indeed possible; its attainment will require the mounting of vigorous efforts to apply to its fullest measure all of our current knowledge of cancer prevention, screening and treatment. This current knowledge base about the causes, prevention and treatment of cancer coupled with the existing network of cancer control resources, such as the Cancer Centers and the Community Clinical Oncology Program and the new information system for physicians (PDQ), form the basis for this vigorous effort in cancer control.

The first step toward this goal is to achieve a major reduction in smoking. Nearly 30 percent of all cancer deaths (over 130,000 deaths per year) are related to smoking. Clearly, reducing the current smoking rate and preventing people from beginning to smoke will have a major impact on reducing cancer mortality. If, by 1980, we can reduce the number of persons who smoke to less than half that who smoked in 1980 we will achieve a 15 percent reduction in lung and smoking-related cancers by year 2000. Although progress has been made in reducing the percentage of adult Americans who smoke, still, in 1983, about one-third of adults were smokers (males 34.8 percent; females 29.5 percent). We must reinforce and accelerate this decline into a consistent, intensive trend in smoking reduction. And, just as important, we must concentrate efforts on reducing the alarming trend toward increased smoking among our Nation's youth. Although these children will not be dying of lung cancer in the year 2000, we will begin to see the effects of their smoking habits by the year 2015 as a major upswing in lung cancer mortality.

Still another large proportion of cancer deaths are related to a controllable cause -- the American diet. In an extensive review of cancer causes, Sir Richard Doll and Richard Peto (1982) estimated that 35 percent of cancer deaths may be attributable to dietary components, with the possible range of effect being 10 to 70 percent. The mid-range estimate of 35 percent would mean that about 150,000 lives could be saved annually with dietary changes. Because the research to test the effectiveness of dietary interventions to reduce cancer incidence and mortality for particular cancer sites is under way, these estimates cannot yet be considered definitive. Yet even the most conservative estimate represents a potentially significant impact of as much as a 10 to 15 percent reduction in total cancer mortality by the year 2000 from prudent dietary changes: decreasing the average American's fat consumption by 25 percent and increasing his or her average fiber consumption by 25 percent.

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Coupled with efforts toward prevention of cancer through reducing smoking and accelerating changes toward more healthful diets, important gains in reducing cancer mortality are possible through earlier detection and treatment of cancer. In particular, mortality for breast and cervical cancer can be greatly reduced through aggressive screening. Breast cancer mortality, which now accounts for 18 percent of all cancer deaths among women, can be reduced 30 percent in women over age 50 who are regularly screened by mammography and physical examination. Although breast cancer screening is effective, the lack of mortality reduction in this cancer site indicates that screening is not occurring at rates necessary to reduce mortality. Similarly, cervical cancer screening is known to be effective: use of the Papanicolaou (Pap) smear can reduce the risk of mortality from invasive cervical cancer by as much as 75 percent according to recent figures. This figure, coupled with current screening figures, yields the estimate that use of the Pap smear for screening could reduce mortality from cervical cancer in the United States by at least 25 percent. Surveys show that, at most, 80 percent of women aged 20 to 39, and 57 percent of women aged 40 to 70 (for whom the risk of cervical cancer is greatest) follow recommended guidelines on screening for cervical cancer. Overall cancer mortality in the year 2000 could be reduced by five percent through these efforts, or a savings of about 25,000 to 35,000 lives per year, depending on the size of the U.S. population in the year 2000.

The third component is in the area of treatment. We have made great progress in improving longevity and in some cancers effecting a cure for many cancer sites. Gains in Hodgkins disease, testicular cancer, breast, colon and other sites, particularly those found susceptible to adjuvant chemotherapy, show great promise. To be effective, these results must be applied in everyday clinical care. SEER data show gains over the past decade, but not gains commensurate with the degree of progress in clinical research. The gap between research and practice must be closed more quickly if we are to progress. NCI estimates that if our existing knowledge were fully applied, cancer mortality could be reduced by 10 to 15 percent. Moreover, if our current rate of advance in clinical treatment is increased so that survival increases by 1.0 to 1.5 percent per year rather than the 0.5 percent progress we have observed over the past decade, we could reduce mortality even more — by an additional 15 percent.

In total, accounting for overlap in the prevention, screening, and treatment strategies, a reduction of cancer mortality in the year 2000 by 50 percent is possible. However, the effort will require intensive actions to reduce smoking; to assure adequate screening; to inform the public of, and assist them in adopting a prudent cancer risk reduction diet; to maintain and expand the network of cancer control resources to speed state-of-the-art cancer care from the clinical research setting to practice; and the resources to continue the research advances that lead to improved treatment regimens.

Question: Since 30 percent of cancer deaths are related to cigarette smoking, a major portion of a cancer reduction program would need to be devoted to reducing smoking. How does NCI plan to reduce smoking by 1990 (Nature, v. 312, November 1, 1984) in order

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to achieve the goal of reducing cancer mortality by the Year 2000? How does NCI plan to convert the older/heavier smokers who are most at risk and hardest to convert? Is NCI planning to develop a chemopreventative agent for treatment of those who have stopped smoking?

Answer: In the NCI plan for smoking control the major objective is to reduce adult smoking prevalence from 33.8 percent in 1980 to 15 percent or less by the year 2000. This objective is based on the assumption that the overall rate of decline in cigarette smoking of about two percent per year can be doubled and that such a rate will apply to men and women alike, if an intensive and coordinated 15-year campaign against smoking is undertaken. The actions recommended to achieve these reductions are based on interventions presently known to be effective in producing cessation, as well as on a broad-scale intervention research program funded by NCI that is expected to produce new and more effective strategies within the next five years that will be suitable for long-scale population implementation.

The recommended actions address eight categories of channels capable of conducting programs or developing policies to influence smoking reduction in the United States:

- National Cancer Institute
- Voluntary organizations
- Physicians and Health Care Providers
- Schools
- Health Care Institutions
- State and Local Health Departments
- Media
- Workplace

A complete description of recommended activities to be undertaken through each of these channels will soon be available in the NCI working document, entitled "Cancer Control: Objectives for the Nation 1985-2000".

The gains in smoking cessation since 1964 (the time of the publication of the first Surgeons General's reports) appear to be primarily in light and moderate smokers (i.e., those individuals smoking less than 25 cigarettes per day). While light and moderate smokers are still important target groups for cessation efforts, because combined they account for about half of the nation's lung cancer each year in smokers, the heavy smoker is also an important target since the risk of lung cancer is much higher in that group. Accordingly, NCI has recently initiated a study to carry out a nationwide community collaborate trial aimed at reducing the smoking prevalence in heavy smokers. The community approach is directed at achieving behavior change in large groups of people by working through that media, the workplace, hospitals and churches. This approach mobilizes broad community involvement. If successful, it will allow for a more realistic opportunity for program continuance, since natural and "real-life" channels are used. Interventions which make changes on the organizational and social level have a greater potential for risk reduction than interventions delivered solely in a restricted clinical setting or on an individual-by-individual basis. Furthermore the

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community-based approach is more cost effective.

Currently, NCI is not supporting projects to develop a chemopreventive agent for treatment of those who have stopped smoking. Epidemiological studies have shown that the risk of lung cancer in those who stop smoking diminishes over time. In 10 to 15 years that risk is reduced nearly to the level of people who have never smoked.

NCI is currently supporting five chemoprevention projects in current smokers who have not been able to stop smoking or in individuals at risk for lung cancer from exposure to other risk factors:

- University of Pittsburgh: Testing the effect of administration of beta-carotene dietary supplements on lung cancer risk in men who smoke a pack or more cigarettes a day.

- University of Washington (Seattle): Testing of the effect of administration of dietary supplements of beta-carotene and retinol on risk of developing lung cancer among high-risk smokers and non-smokers who have had asbestos exposure.

- University of Washington (Seattle): Testing of the effect of administration of dietary supplements of beta-carotene and retinol on lower risk smokers with no history of asbestos exposure.

- University of Alabama (Birmingham): Testing of the effect of dietary supplements of folic acid and vitamin B_{12} on pathological changes in the bronchial epithelium.

- National Public Health Institute of Finland and the National Cancer Institute (collaborative project): Testing of the effects of beta-carotene and/or alpha tocopheral (vitamin E) on lung cancer risk in male smokers.

ADVANCES IN CURING CANCER

Question: A small but growing number of distinguished analysts are challenging statements made by NCI that great advances have been made by the Institute in curing cancer. The skeptics suggest that the survival rate gains of recent years are partly or perhaps largely a statistical mirage, caused more by changes in the way cancer is detected and defined, than by any real gains in curing the disease. What is NCI's response to these serious charges?

Answer: NCI's major source of data on cancer trends is the Surveillance, Epidemiology, and End Results Program, known as SEER. The Program has collected data on cancer incidence, mortality and survival continuously since 1973 and, with the recent addition of New Jersey to the system, covers some 12 percent of the United States. The SEER methods for data collection are highly regarded

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worldwide and the data is of the highest quality. The trends observed in the data are clear: relatively stable incidence except for lung cancer; increased survival for all sites cancer. The trends for specific cancer sites has been the subject of critical interpretation. We welcome the analysis and believe that through such analysis we find clues to the reasons behind the trends in cancer, and indicators of the effectiveness of our cancer control efforts.

The critics who interpret the observed improvements in cancer survival rates as being due to changes in definition or detection are referring primarily to survival changes noted for prostatic cancers among males and endometrial cancers among females.

For prostate cancer, the incidence rate has increased rapidly in the past few years. This has led to the speculation that some of the survival increase may be due to diagnosis of cancers that would not have been diagnosed 10 to 20 years ago, and which would have gone unnoticed even at death. The fact that cancer mortality rates have not increased as rapidly as incidence rates suggests that either the critics are correct (that is, that incidence has been increased by essentially benign tumors), or that there has been a true increase in the incidence of the disease and, to achieve the non-increasing mortality rate, there must have been a change in treatment effect resulting in improved survival.

In the first case, if the critics are correct, then an examination of patients by stage of disease at diagnosis should reveal that there is a shift of patients into the category of localized or less severe disease with all improvement in survival occurring in this group.

In fact, a comparison of data for patients diagnosed in 1960 versus those diagnosed in 1981 reveals that essentially the same proportion of cases were diagnosed with localized disease in the two time periods:

Distribution of prostate cancer by stage at diagnosis, whites, 1960 and 1981

State	1960	1981
Localized	64%	67%
Distant	19	19
Unknown	6	3
All Stages	100%	100%

Further, when one examines relative survival rates over time, improvements in survival have been noted for each stage group:

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Five-year relative survival rates for prostate cancers by stage at diagnosis, whites, 1960 to 1981

Stage	1960/1963	1970/1973	1973/1981
Localized	65	79	81
Regional	55	62	71
Distant	12	23	29
All Stages	52	64	69

Thus, not only have there been improvements over time for each stage group, but the most striking improvement in the 1970s has occurred among cases diagnosed with regional and distant disease.

These data show that improvements in survival for prostate cancer cannot be accounted for on the basis of early diagnosis and cannot be dismissed as a statistical mirage. Further, there has been a shift in treatment practice for prostate cancer between 1973 and 1981, as documented by NCI data from the Surveillance, Epidemiology, and End Results (SEER) program, with fewer patients receiving hormonal therapy and more receiving surgery and radiotherapy.

On the other hand, some have noted that the increase in survival for cancer of the endometrium for patients diagnosed in the late 1960s and 1970s may be associated with the greatly increased use of postmenopausal estrogens during that period. The hypothesis is that cases of endometrial-like cancer were associated with estrogen use and that, for these cases, nearly all patients would survive. Therefore, if the hypothesis holds, misdiagnosis of the endometrial-like cancers would lead to higher survival estimates for endometrial cancer. In fact, when estrogen use in postmenopausal women was advised against by the Food and Drug Administration, the incidence of the cancer fell as did survival -- consistent with this hypothesis.

We and the critical analysts agree with explanation of the survival increase and decrease in endometrial cancer. However, since endometrial cancer accounts for only five percent of all cancers, its effect on the overall cancer survival rate is minimal.

Our data indicates that this overall cancer survival rate has increased and that the results are not a statistical mirage, nor can they be based solely on our data systems. The overall survival rate is the combination of survival rates for the individual cancer sites. Progress takes place at different rates for each site and we would expect this to be the case. Yet, the overall rate of advance has been very similar from the 1960s through the 1970s. We welcome the scrutiny of the cancer data so that we can identify even more thoroughly our progress and trace areas where progress in lacking. But it must be made clear that trends in cancer take years to assess and that they must be coupled with clinical research and examination of health systems trends for the most complete explanation of the data.

We believe that trends in survival are real and not a

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statistical mirage. Our data reflect national trends and we welcome the opportunity to work with other scientists on the interpretation of these data to further improve our rate of progress.

GRANT FUNDING

Question: Several Institutes within NIH are considering changing from a three-year grant funding period to a five-year grant funding period. What is NCI' position on such a change? Would such a change be an overall one, or only available to more senior research scientists with a proven track record?

Answer: The National Cancer Institute recently announced a new mechanism, the Outstanding Investigator Grant, which would be a competitive, peer-reviewed grant of sever years of support, awarded to investigators of acknowledged achievement and clear potential in cancer or cancer-related research. Even prior to the publication of that initiative, NCI, like many other Institutes of the NIH, favored five-year rather than three-year awards, unless there was a clearly stated reason for not doing so. In this regard, NCI position would be favorable regarding such a change, recognizing that future year commitments from these longer awards could reduce the Institute's flexibility in the award of new and competing grants.

CANCER AND MINORITIES

Question: We have been told that there are major differences between cancer incidence and mortality in whites compared to some minority populations.

What are these differences?

Answer: The majority of the available cancer data on minorities is on Blacks. Blacks experience cancer incidence higher than the white population for a number of cancer sites:

- Cervix
- Esophagus
- Larynx
- Lung (male)
- Multiple myeloma
- Pancreas
- Stomach

Blacks experience cancer mortality higher than in the white population for the following sites:

- Cervix
- Esophagus
- Larynx
- Multiple myeloma
- Prostate

An article "Cancer Patient Survival Among Ethnic Groups in the United States" was published in the Journal of the National Cancer Institute (JNCI) in August 1984 (pages 341 to 352). It

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examined the cancer survival of eight racial ethnic groups in the United States: Whites, Hispanics, Blacks, American Indians, Chinese, Japanese, Filipinos, and Hawaiians. Data came from the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute for the years 1973 to 1979.

Overall five-year survival rates were roughly the same for Whites, Hispanics, Chinese, and Hawaiians. The Japanese experienced the highest survival rates for some sites. Blacks and American Indians generally experienced the lowest survival rates. Filipinos had similar survival experiences as Blacks. However, the general trends often vary when discussing specific cancer sites. Blacks have a 12 percent poorer survival rate (38 percent versus 50 percent) than Whites for all cancer sites combined. Blacks may experience survival rates that are 10 to 30 percent lower than in Whites for selected cancer sites.

Question: Why do they exist?

Answer: The exact reasons for these differences are unclear, and additional research is needed to define these more explicitly. Present knowledge suggests a variety of contributing factors which include:

- Risk factors/exposures such as smoking and occupation.

- Socio-economic factors such as:

    - Health Resources: Access, Availability, Utilization;
    - Knowledge, Attitudes, and Practices of primary and secondary cancer prevention methods; and
    - Quality, Continuity, and Compliance with cancer treatment.

- Late stage of disease at diagnosis.

- Delay in seeking treatment following symptom onset.

Question: What are you doing about them, and is that everything that should be done about them?

Answer: The cancer experience of Blacks has been a concern of the NCI for some time. Since the Third National Cancer Survey (1969 to 1971) and the subsequent establishment of the Surveillance Epidemiology and End Results (SEER) program it has become possible to quantify the site-specific differences in incidence rates between blacks and whites in this country. Blacks of both sexes have elevated risks for cancers of the esophagus, stomach, pancreas, lung, and multiple myeloma, along with a substantial excess among blacks of prostatic cancer and invasive cervical cancer. Currently the NCI is attempting to assess the reasons for the excess of lung cancer among black males and for the excess of cancers of the uterine cervix among black females via a large case-control study of lung cancer in New Jersey and collaborative study of the uterine cervix involving five cancer centers. A field investigation of a "hot spot" of cancer mortality for stomach cancer in blacks in Southern Louisiana is also currently nearing completion. In addition, a study was conducted in esophageal cancer among blacks in the District of Columbia by the NCI several

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years ago which raised some specific suggestions about possible reasons for the differences between blacks and whites. A pertinent new hypothesis suggested by this study is related to specific measures of nutritional deficiency as potential risk factors for esophageal cancer. However, the study design did not allow a direct assessment of which risk factors might explain the excess among blacks. Based on the differences in site-specific cancer incidence rates between blacks and whites and on what is currently under investigation, there is currently a substantial need for analytic investigations to address the reasons for the excess risk among blacks of four types of cancer -- esophagus, pancreas, prostate and multiple myeloma. Consequently, a relatively large population-based study encompassing blacks and whites has begun and is addressing several major concerns with respect to each individual site as well as evaluating directly the reasons for black/white differences in incidence. For example, to evaluate the role of tobacco, alcohol, diet, and other factors in the black/white differences in esophageal cancer, a population-based case-control study is being planned. Only males will be included because the much lower rates among females make the assembly of sufficient numbers of cases impractical. The study will be large enough (600 cases) to enable the assessment of dietary factors within each of several tobacco-by-alcohol strata for both blacks and whites. It will also provide, for the first time, an adequate evaluation of smoking among non-drinkers, drinking among non-smokers, and the role of smokeless tobacco, as well as further quantify the interaction between these risk factors. Furthermore, it will enable determination of whether tobacco and alcohol affect blacks and whites equally, and of the extent to which intake of these substances accounts for the racial differences in incidence.

Additionally, in 1984, a study to investigate differentials in survival between black patients and white patients for cancers of the breast, corpus uterus, colon and prostate was started in three locations: San Francisco, New Orleans and Atlanta. The study protocol has been developed and patients are now being entered into the study. The addition of a fourth study location is currently being considered. This study is expected to provide significant information relevant to the development of targeted approaches to improve this situation.

In conjunction with these studies the NCI recently convened a working group of scientists and health professionals to develop specific recommendations for approaching this problem. The first initiative to arise from this planning is a proposal to develop the Black Cancer Control Research Network. It is the intent of this Network to become the centerpiece for cancer control research directed at black populations. It will be national in scope and conduct cooperative studies directed at prevention, screening and early detection, and improved patterns of treatment.

A second working group is planned for June to define an agenda for more effective application of current knowledge to reduce those differentials in cancer rates that affect blacks adversely. A similar process will follow for rate differences in other minority groups. As results come in from these programs and advice is received from minority working groups, new initiatives involving additional resources will be implemented. For example,

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at this moment two potential minority consortiums have submitted requests for planning grants which could lead to the establishment of a cancer centers consortium. One application is from Drew University (Los Angeles) which will serve as the headquarters of joint effort from Meharry University, Morehouse University and Drew University. The other request comes from the University of Medicine and Denistry of the University of New Jersey. They propose a consortium of the entire state located in Newark, New Jersey with a large population of blacks and Hispanics.

Further initiatives include, funding for a community intervention program to reduce cigarette smoking in low income Hispanic populations in South-Central Texas. It is estimated that more than 70,000 persons will be directly affected by the program, and as many as 2,500,000 will be exposed to the media campaign.

Two other projects addressing Hispanic populations are planned. In the San Francisco area 1,700 Hispanic smokers will be recruited for specially designed cessation programs. In the New York area 30 junior-high and intermediate schools with at least a 50 percent Hispanic enrollment will be involved in a program to evaluate the effectiveness of a classroom smoking prevention program. Two thousand families of Hispanic students will be interviewed to determine the prevalence of smoking as well as attitudes toward smoking within the home. In both of these studies materials will be designed that address social and cultural variables specific to Hispanic smokers.

A similar study focusing on smoking cessation among black populations will impact some 2,400 adult smokers in the Southeastern U.S. who will be recruited through their life insurance programs.

The NCI also supports minority biomedical research at approximately 36 minority institutions through its Comprehensive Minority Biomedical Program (CMBP). Recently, two new initiatives have been created: 1) the Minority Investigator Supplement, to encourage participation by underrepresented ethnic American minorities, and 2) the Minority Satellite Supplement, to promote the participation of minority patients in clinical trials and treatment programs, especially at minority institutions and hospitals. The expanded scope of these efforts is expected to yield significant information relevant to prevention, detection, treatment, and biology of cancer.

Finally, as part of its Cancer Prevention Awareness Program, the Institute is specially targeting minority audiences, particularly blacks and Hispanics. In May, NCI will launch a mass media prevention program aimed at black audiences, and has developed publications especially for black audiences. In addition, many of the most commonly requested NCI publications are also available in Spanish for distribution to Hispanic groups. The large cancer centers which collaborate with NCI in providing educational support to the public are targeting black and Hispanic audiences in their particular regions for cancer education programs. In addition, the NCI-supported Cancer Information Service, which provide the public with a toll-free telephone number for use in obtaining cancer information, has counselors who speak Spanish staffing offices that service Hispanic populations.

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Questions Submitted by Senator William Proxmire

MORTALITY RATES

Question: Dr. DeVita, as you know there has been a great deal of controversy over your success in the fight against cancer. For example some critics say your improved cure rate results from a more sophisticated database — better counting -- and earlier detection.

I'd like to focus on some specific figures. Could you give us the age-adjusted cancer mortality rate per 100,000 population for the three latest years for which statistics are available and explain any significant changes?

Answer: It is a fact that our data systems have improved. We now collect detailed statistics from some 12 percent of the United States' population. Our methods and data are available to researchers worldwide, and we welcome and encourage collaboration. The statistics from our Surveillance, Epidemiology and End Results Program, known as SEER, set a world standard for excellence and quality of reporting.

Success in the fight against cancer is clear, both from our overall figures and the data on specific cancer sites. We have seen the five-year survival rate -- the likelihood that a person will survival at least five years after being diagnosed with cancer -- increase dramatically from 38 percent in 1960 to 1963, to 49 percent of patients diagnosed from 1976 to 1981, to greater than 50 percent for patients diagnosed today. We have seen the survival rate from Hodgkin's disease increase from 40 percent in 1960 to 1963 to 74 percent in 1976 to 1981. The survival rate for testicular cancer has increased from 63 to 87 percent over the same period of time, and the rate for childhood cancers has jumped dramatically from 28 to 60 percent survival, again over the same nearly twenty-year time span.

You asked specifically about mortality rate figures. It should be pointed out that mortality rates vary directly with incidence rates and inversely with survival rates. Therefore, if the incidence rate for cancer increases, that is, if the number of new cancer cases per year per 100,000 persons increases, as it has for lung cancer — because of the tremendous increase in smoking some 20 to 40 years ago -- the mortality rate will increase in direct proportion if survival remains the same. However, if survival is increasing at a rate faster than incidence, the mortality rate will not rise as steeply as incidence and, in fact, may fall.

Now, turning to mortality data, the latest year for which mortality data are available from the national center for Health Statistics in 1982. The mortality rates (age-adjusted to the 1970 U.S. population distribution) for 1980 to 1982 are 168.1, 167.1 and 168.4. However, a three-year time span is not long enough to deduce changes in cancer mortality rates. As shown in the following table, if we go back to 1960, the mortality rate was 158.4. This represents an increase in the overall mortality rate of 6.3 percent or 0.3 percent per year. If lung cancer were eliminated as a cause of death, the mortality rate for all other

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sites in 1960 would have been 147.8 deaths per 100,000 persons and 124.4 in 1982. Thus, with the exception of lung cancer, the cancer mortality rate has decreased by 15.8 percent, or 0.8 percent per year, between 1960 and 1982.

The mortality data also indicate that the mortality rates for lung cancer in men has begun to level off. There was an increase of 6.4 percent from 1970 to 1972, but from 1980 to 1982 the increase in lung cancer mortality among women, which increased by 9.4 percent between 1980 and 1982.

To summarize, recent mortality data show a consistent downward trend for all cancer sites excluding lung cancer. The fact of this downward trend and the relatively constant incidence (from 1974 through 1981, Table 2) we see in all sites combined excluding lung cancer, are consistent with the hypothesis of increasing survival. The increase in lung cancer is due to the increase in the number of persons who smoke that occurred over the period from 1945 to 1965.

We welcome the collaboration of others in the ongoing analysis of this data, and the further interpretation and explanation of the reasons behind the trends.

Table 1

AGE-ADJUSTED (1970 U.S. STANDARD) CANCER MORTALITY RATES (DEATHS PER 100,000 PERSONS) IN THE UNITED STATES FOR ALL SITES AND ALL SITES MINUS LUNG, ALL RACES, 1960 TO 1982

YEAR	ALL SITES	LUNG	ALL SITES MINUS LUNG
1960	158.4	10.6	147.8
1970	162.0	31.9	130.1
1971	161.9	33.0	128.9
1972	163.4	34.2	129.2
1973	162.0	34.8	127.2
1974	163.1	36.0	127.1
1975	162.2	36.8	125.4
1976	164.5	38.1	126.4
1977	165.1	39.2	125.9
1978	166.1	40.4	125.7
1979	166.1	41.1	125.0
1980	168.1	42.5	125.6
1981	167.1	42.9	124.2
1982	168.4	44.0	124.4
Percent Change 1960 to 1982	+6.3	+315.1	-15.8

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Table 2

AGE-ADJUSTED (1970 U.S. STANDARD) CANCER INCIDENCE RATES (CASES PER 100,000 PERSONS) IN THE UNITED STATES FOR ALL SITES AND ALL SITES MINUS LUNG, ALL RACES, 1973 TO 1981

YEAR	ALL SITES	LUNG	ALL SITES MINUS LUNG
1973	317.5	42.4	275.1
1974	329.6	43.6	286.0
1975	330.0	45.2	284.8
1976	334.9	47.7	287.2
1977	334.1	48.8	285.3
1978	333.3	49.9	283.4
1979	336.5	50.7	285.8
1980	338.8	52.0	286.8
1981	342.6	53.2	289.4
Percent Change 1973 to 1981	+7.9	+25.2	+5.2
Percent Change 1974 to 1981	+3.9	+22.0	+1.2

Source: NCI Surveillance, Epidemiology, and End Result Program.

CANCER AND DIET

Question: Dr. DeVita, a recent edition of the publication Nutrition Action had an editorial that focused on your nutrition education campaign. The editorial was critical of the Department of Agriculture's efforts to change some of your nutritional guidelines before publication. The editorial stated that a page had been intentially torn out of a pamphlet you issued titled "Good News, Better News, Best News: Cancer Prevention" and speculated that you had been pressured to do this by USDA.

Could you enlighten us as to the interaction between the Cancer Institute and the Department of Agriculture and also tell us whether a page was removed from one of your publications and why?

Answer: NCI staff recently developed a publication, "Diet, Nutrition, and Cancer Prevention: A Guide to Food Choices". As this publication was developed, staff at the USDA, particularly in the Human Nutrition Information Service, reviewed the drafts and provided comments. USDA staff also provided data included in the publication's appendix listing fat and caloric content of some foods.

Another publication of NCI, "Good News, Better New, Best News: Cancer Prevention", was reprinted last September to include two tearout inserts. These inserts were essentially reprints of the fiber and fat chapters in a draft of the "Guide to Food Choices" publication. The insert on fat included a statement that NCI recommends that individuals receive no more than 30 percent of their calories from fat. Joint dietary guidelines of the Department of Agriculture and the Department of Health and Human Services recommend reducing the amount of calories from fat, but do

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not recommend a specific level. NCI, therefore, changed the wording in its draft of the "Food Choices" pamphlet to be in line with the joint USDA/DHHS guidelines, but did also mention that a committee of the National Academy of Sciences recommends that no more than 30 percent of calories come from fat in the diet.

In order that the "Good News" pamphlet remain consistent with other NCI publications and the USDA/DHHS guidelines, the insert on fat was removed from "Good News" before it was mailed.

CANCER BIOLOGY

Question: Dr. DeVita, last year's justifications indicate you planned to spend $13,260,000 on cancer biology research and development contracts in FY 1985. Funding for these contracts has since been reduced to $6,682,000 despite the fact that the Congress substantially increased your budget request. Can you tell us why?

Answer: The 1985 Congressional Justification included contract support for the Frederick Cancer Research Facility of which a portion was applicable to the Cancer Biology research thrust. Since that time, significant new research programs have developed in the Cause and Prevention research thrust, notably oncogene research and carcinogen induced mutagenesis. Ongoing Cause and Prevention research programs such as endogenous cell growth and cell regulatory factors, have been strengthened. These emerging research areas in Cause and Prevention resulted in a redirection from the Cancer Biology thrust to the Cause and Prevention thrust. In addition, resource support contracts in immunology research and tumor biology were also decreased.

RESEARCH AND DEVELOPMENT CONTRACTS

Question: According to this year's justifications you will be spending exactly the same amount in each of your research and development contract areas -- treatment research, cancer biology and so forth -- in FY 1986 as this year. Why don't you anticipate any change in these costs?

Answer: The 1986 President's Budget policy was to freeze extramural programs, other than research project grants, at the 1985 funding level. Thus, the distribution of funds has remained constant.

WITHIN GRADE INCREASES

Question: On page 20 of your justification you indicate your base for within grade increases in 1985 is $93,451,000. Yet your 1984 base was only $45,324,000.

Can you explain the reason for the doubling of your base?

Answer: The amount to be shown in the base column has been under analysis and discussion during the last year. In the 1985 Congressional Justification, the amount shown for the within grade increases base reflected our estimate of the salaries of general schedule employees who would be receiving within grade increases during the coming year.

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However, in the development of the 1986 Congressional Justification, we felt a more comprehensible presentation in the Summary of Changes table would be to present the entire payroll for the Institute for all items related to personal services receiving increases or decreases. Thus the estimate for the base for the cost of the comparability payraise also changes in magnitude between the two Congressional Justifications. This method of presentation was adopted since it is consistent with the presentation of the changes in extramural programs shown in the Summary of Changes analysis. In the extramural programs, the base amounts reflect the entire program funding level.

Questions Submitted by Senator Quentin N. Burdick

Question: Dr. DeVita, my questions concern the effect of the new Medicare DRG reimbursement system on cancer treatment and on clinical research.

Is there currently any cooridination between the National Cancer Institute and the Health Care Financing Administration in determining the DRG rates for cancer-related illnesses? Is the expertise at NCI utilized either by HCFA or by the Prospective Payment Assessment Commission?

Answer: Staff expertise at the NCI and the National Center for Health Services Research is currently being utilized to study the impact of Medicare's new Prospective Payment System on the NCI's clinical research program. This study, the Hospital Cost and Clinical Research Project (HCCRP), will assess the adequacy of the current DRG-based reimbursement rates for both cancer patients participating in NCI-sponsored clinical trials and cancer patients receiving "usual" hospital care. It is expected that the results from this project ultimately will be utilized by HCFA in its evaluation of the Prospective Payment System.

Question: I understand three of the DRG rates that relate to cancer care are considered by some, at least, to be much too low. These are DRGs 401, 403 and 410. Will you have any input into reassessing the reimbursement levels for these DRGs in the coming year?

Answer: The Hospital Cost and Clinical Research Project (HCCRP) is studying the DRG rates for all cancer-related illnesses, including DRGs 401 (lymphoma or leukemia with minor operating room procedure for patients over age 69 and/or complication or comorbidity), 403 (lymphoma or leukemia for patients over age 69 and/or complication or comorbidity) and 410 (chemotherapy). One part of this study will compare the hospital costs of treating patients enrolled in clinical trials with the costs of treating patients with similar diagnoses receiving "usual" care. In turn, these costs will be compared to the actual DRG-based reimbursement rates established by HCFA. The first results will be made available in about one year, although the project is not scheduled for completion until late 1987.

Question: I also want to ask you about the Community oncology programs. As you know, this committee has long supported the community clinical oncology program and we have urged you to

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see that this program expanded geographically so that people in all parts of the country could benefit from it.

I am quite concerned about the impact the DRG reimbursement system may have on clinical research at the community level. Many are saying that clinical research will be severely curtailed under the new Medicare reimbursement system because the DRGs do not allow for the extra costs involved in this research. Could you please comment on this situation and tell me what NCI might be willing to do to help? You pay for clinical research in other projects; what would be involved in covering those costs for the community cancer programs?

Answer: The costs related to clinical research can be divided into 1) costs of patient care and 2) costs of research (data management and research-related laboratory tests, e.g., monitoring new drug toxicity). Community programs are primarily involved in studies in which standard therapy compared to a new promising treatment regimen and the only research costs are those for data management. We presently support the data management efforts.

Although some medical practitioners believe that treating patients enrolled in clinical trials is more costly than treating patients without the benefit of clinical protocol, it is important to note that there is no scientific body of knowledge that supports this supposition. The National Cancer Institute (NCI) and the National Center for Health Services Research (NCHSR) are collaborating on a project to determine how well hospital costs are covered under the Prospective Payment System (PPS) and if the NCI clinical research programs are adversely affected by this new system.

Questions Submitted by Senator Daniel K. Inouye

Question: The Community was very pleased to learn that the President's Cancer Advisory Panel held extensive field hearings in Honolulu, Hawaii. Native Hawaiians have the highest proportion of cancer of any subpopulation in our nation. What recommendations does NCI have, based on the Honolulu hearings, for how to affirmatively address the pressing needs of these native American peoples?

Answer: The President's Cancer Panel meeting in Honolulu, Hawaii, was made aware of the extreme diversity in culture, and other factors which may act as barriers to optimal cancer care for these native American people in the Pacific. Although epidemiology has played a major role in research efforts in the Hawaiian Islands in the past, this has focused primarily on major differences in cancer incidence among the various ethnic groups in the Islands. The NCI has funded a program project grant (Dr. Lawrence Kolonel, Principle Investigator) to help study this program. In addition, for the last 10 years the NCI has supported a cancer center in Hawaii, which has been involved with both epidemiologic and clinical research in the past. Presently, there is a conference grant under review by the NCI which will address the special cancer control needs of the smaller islands in the East Pacific. It is recognized that the sophistication and facilities available in

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Honolulu may not be available in some of the smaller islands, and some attempt to improve cancer control first by defining the extent of the problem and then by developing future intervention programs is contemplated.

Question: Further, what activities does NCI have, or what future plans are being considered, to explore the needs of the various native American peoples throughout the Pacific Basin Region. The Committee understands that there are also major problems with these other residents.

Answer: At this moment the NCI is formulating a grant instrument to support a cancer center consortium concept which would lend itself to the special problems that exist in the Pacific Basin Region. Such an instrument will support the collaborative efforts of cancer centers, departments of health, universities and other health agencies to conduct studies in cancer control.

Question: Last year the Committee expressed concern that cancer programs targeted towards children may not be receiving sufficient priority. What plans does NCI have for this particular population?

Answer: The treatment of cancer in children has provided unique insights as a model for therapeutic success in the treatment of cancer for both children and adults. The curative potential of combination chemotherapy was pioneered in studies of childhood leukemia. The effectiveness of multimodal treatment (surgery, radiotherapy, and chemotherapy) was established in the treatment of Wilm's tumor (a kidney tumor of childhood). Verification of the hypothesis that adjuvant chemotherapy could cure has been strengthened by studies of osteogenic sarcoma. Indeed, studies completed this year confirm that adjuvant chemotherapy is highly effective in this setting.

One of the truly remarkable achievements in cancer treatment is improved curability of childhood leukemia. It is sobering to realize that in the mid-fifties only 103 children with leukemia who had survived more than five years could be identified worldwide, and that all of these patients had received some form of then-experimental chemotherapy. This survey suggested that drug treatments could actually cure cancer. This was a controversial notion in the 1950s, but an every day occurrence today. In fact, at least half of the children diagnosed with leukemia in 1985 will be cured. For this reason, much research in leukemia seeks to treat patients with modified therapies to minimize side effects without compromising cure. Again, the CCSG has divided children into good, intermediate, and poor risk categories based on clinical characteristics and is treating the leukemia with regimens of parallel intensity. The POG will undertake similar research classifying risk on the basis of immunologic rather than clinical characteristics.

The Institute's Surveillance, Epidemiology and End Results program monitors cancer survival at a national level and has documented substantial decreases in mortality for all the major childhood cancers. For example the survival of all children with cancer (that is, all sites combined) has increased from 27 percent

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in 1963 to over 60 percent in 1981. Clearly, clinical research has had a major impact on cancer survival in children at a national level.

In treating all cancers, the first goal is to develop effective therapies. When a cancer kills every patient, the highest priority is that new therapies be effective. Once effective therapy is available, modifications of treatments are required to minimize late side effects, both physical and psychosocial. Future research in childhood cancer places considerable emphasis on minimizing toxicity while maintaining high cure rates. For example, the Children's Cancer Study Group (CCSG) is testing the hypothesis that preoperative chemotherapy may allow for less radical surgery and preservation of the limb in patients with osteogenic sarcoma, while the Pediatric Oncology Group (POG) is studying whether radiotherapy to large tumor masses is necessary for cure in patients with non-Hodgkin's lymphoma.

Much of the research in childhood cancer is funded through the Cooperative Agreement mechanism (U10). This funding instrument is particularly suited to provide timely answers to scientific questions for studies of less common cancers, such as pediatric malignancies. More recently, collaboration between cooperative clinical trials groups has increased and these "Intergroup Studies" (such as the Wilm's Tumor Intergroup Study) can provide even greater cost effectiveness and efficiency. A contract study will support the early evaluation of promising new drugs in children and simultaneously address the issue of differences in drug pharmacology in children versus adults. The pooling of scientific talents, patient resources, and statistical expertise results in a powerful investigative instrument for important problems like childhood cancer. Although pediatric malignancies are relatively uncommon, patients who are cured now have the whole of their productive lives ahead of them, making this research appropriately high in the priorities of the Institute.

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NATIONAL INSTITUTE OF DENTAL RESEARCH

STATEMENT OF DR. HARALD LÖE, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

GILBERT D. PRESS, BUDGET OFFICER, NATIONAL INSTITUTE OF DENTAL RESEARCH

BUDGET REQUEST

Senator WEICKER. Our last witness this morning will be Dr. Harald Löe, Director of the National Institute of Dental Research. The National Institute of Dental Research is requesting a budget of $93 million in Fiscal Year 1986, $7 million less than appropriated in fiscal year 1985. Despite borrowing $4.5 million from 1985, the 1986 budget is still below the 1985 appropriated level of $1 million. It is nice to have you here, Dr. Löe.

Dr. LOE. Mr. Chairman, I have with me Mr. Gilbert Press, the Budget Officer of the NIDR.

HIGHLIGHTS

You have heard from Dr. Wyngaarden, and from others, that genetic engineering has proceeded at a much faster pace than was ever anticipated. Last year I reported on the cloning of a gene that codes for a protein essential in the formation of tooth enamel. This year I am pleased to announce dramatic headway in the development of an antiherpes vaccine. The vaccine is a hybrid of the familiar vaccine against smallpox and a gene that codes for a surface protein of herpes type 1 virus, the cause of cold sores. The vaccine not only prevents the herpes infection, but also reduces the risk of the virus taking up residence in the nervous system. It is this habit of all herpesviruses to remain latent in nerve cells, and later reactivate, that causes flare ups of these diseases.

I might add that the experimental vaccine is the first demonstration of a genetically engineered vaccine to prevent latency. A further cause for excitement is that the new vaccine, while effective against type 1 herpes, also provided impressive protection against genital herpes, caused by the type 2 herpesvirus.

We are also using biotechnology to accelerate development of an anticaries vaccine. Again, investigators are probing caries bacteria to isolate proteins and their parent genes that have immunizing potential.

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Vaccines are, of course, ideal weapons when you know the enemy, when a sizable number of people are at risk, and when they have not yet been infected.

When disease is already present or there is no special causative organism known, the search goes on for earlier diagnoses, better treatments, and cures.

At the NIDR our strategies are increasingly tailored to populations at risk. Thus, we are streamlining fluoride programs to prevent caries in handicapped and other compromised individuals. We are pressing for new antimicrobials and other antiplaque agents that could prevent or reverse early stage periodontal diseases. We are perfecting computerized x ray methods and exploring other methods to detect developing disease. Scientists in our mineralized tissue branch have developed a simple means of isolating bone-forming cells from patients—a technique that should aid diagnosis and shed light on several crippling bone and joint disorders.

We are widening the horizons of dental research as it moves from a more traditional focus on the teeth, to an exploration of the total role of oral tissues in human health and well-being. We are particularly aware of this enlarged focus as we turn our attention to the adult and the elderly.

At this moment clinical examiners are at work sites and at centers for the elderly throughout the country to conduct oral examinations of close to 20,000 Americans.

We have also undertaken a collaborative project with the National Institute on Aging and the Veterans Administration to explore oral health needs in the elderly and to delineate ways in which our three organizations can share resources, manpower, and expertise.

These activities reflect goals described in the NIDR long-range research plan of seeking to broaden our partnerships within and outside the Government, with academia, with industry, and with the public itself. Toward that end, we are mindful of the need to ensure the manpower to continue the work. Accordingly, I am delighted to report that we have been able to expedite implementation of the new Dentist Scientist Awards, a program that will significantly strengthen our research capabilities. This is our way of ensuring that the best of research is moved by the brightest of minds—and where it is most needed: the gainers will be all people, of all ages, everywhere.

Mr. Chairman, I will be happy to answer any questions that you might have.

PREPARED STATEMENT

Senator WEICKER. Thank you. Your statement will be inserted in the record before we proceed.

[The statement follows:]

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Statement of Dr. Harald Löe

It is a pleasure to appear before the Committee again and to report on the past year's progress and our current plans. Last year at this time we announced the publication of our Long-Range Research Plan, Challenges for the Eighties. We emphasized our intention to use the Plan to guide us in moving dental research ever closer to a science of prevention, so that future generations of Americans, of all ages, need never lose their teeth to disease. We mentioned specific means we intended to use to accelerate achievement of those goals: forging deeper partnerships with the academic, professional and business communities; using the best methods from the behavioral and social sciences to promote more rapid transfer of new science and technology; doing our utmost to maintain the excellence of our intramural research program; and establishing new mechanisms to ensure an ongoing supply of research personnel—especially dentist-scientists, clinically trained investigators who are able to link basic biomedical findings to clinical needs and applications. Let me summarize now what we've been able to accomplish this year on all these fronts.

The NIDR is pleased to announce major progress in the development of vaccines against herpes simplex virus infections and dental caries.

I would like to tell the herpes story in some detail in order to illustrate how fully dental research is now exploiting molecular biology recombinant DNA and monoclonal antibody techniques. NIDR investigators, in collaboration with scientists at the National Institute of Allergy and Infectious Diseases, have made a recombinant vaccine that weds a tried-and-true vaccine against smallpox with genes that code for proteins derived from the herpes simplex virus type I, the cause of cold sores. Our investigators have developed an animal model of herpes infection in mice. Tests have now shown that not only are mice inoculated with the new vaccine protected against infection when exposed to large quantities of herpesvirus, but in a majority of cases the vaccine also prevents the virus from taking refuge in the nervous system. It is this ability of herpesviruses to lie latent in nerve cells and periodically reactivate that causes the recurrences that plague sufferers of cold sores and genital herpes. I might add that an unexpected finding from these studies was that the new vaccine, made from genes derived from herpes type I viruses, also conferred substantial immunity to type II, or genital herpesviruses. Needless to say, we are pressing efforts in this area, and hope to move ahead quickly to clinical studies in human subjects.

In the case of the anticaries vaccine, I should note that over the past several years many NIDR-supported grantees have been testing factors derived from Streptococcus mutans, the principal cause of dental caries, for their immunizing potential. Now, a world-renowned molecular biologist has isolated a surface protein of these bacteria that enables them to stick to tooth surfaces as well as to clump together to form dental plaque. The gene coding for this factor has been cloned and will be spliced into a weakened (non-infective) form of certain intestinal bacteria. The idea is to use this recombinant form as an oral vaccine to stimulate immunity to caries via the gastric route.

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In talking about vaccines, we must remember that the target populations must not yet be infected with the disease in question. The aim is to prevent disease in future generations. Unfortunately, there already exists a heavy burden of oral infections and other serious oral disorders that we must continue to fight with better diagnoses, treatments and cures.

In the case of tooth decay we are exploring ways of aiding the body's own natural repair mechanisms by incorporating specific minerals, including fluoride (along with buffers) in a mouthrinse or lozenge. Such regimens could actually result in tooth enamel that is more resistant to decay by modifying the crystalline structure of enamel. Furthermore, we are exploring the potential of this approach to enhance the resistance of all the hard tissues of teeth--the dentin that underlies enamel and the cementum that covers the root of the tooth. In adults and in the elderly, surface enamel is often worn thin and the cementum over the tooth root is exposed because of gum recession. The result is that these tissues become vulnerable to decay (called root caries in the case of infection of the cementum). Very little is known about the bacteria that cause root caries, and because there is evidence to suggest that this disease is on the rise, the NIDR has established several specialized caries research centers in a concerted effort to understand the natural history of the disease. Other grantees and intramural scientists continue to explore the ways fluoride works to protect adults' teeth against decay. Some are refining and testing the fluoride slow-release device that can be fitted onto single teeth to provide a constant, low concentration of fluoride in the oral cavity. We consider this device our best bet for preventing decay in the handicapped and others at high risk.

We are mindful of the need to monitor the level of fluoride intake in the body from the natural environment and from the many products now available. We are looking at fluoride both from the perspective of total intake in food products in sample groups as well as how fluoride is metabolized and cleared from the body. I must add, however, that even in parts of the world where fluoride concentrations in water are high, there appear to be no serious side effects.

We have stated to this Committee and in our Long-Range Plan that the Institute will expand research on the periodontal diseases, considered to be the major cause of tooth loss in adults. Part of that effort entails classic epidemiology, and I am pleased to report that, in early February of this year, the NIDR began a major nationwide survey on oral health in working adults and in the elderly. Over the course of the year clinical examiners will conduct oral examinations of 15,000 adults in America. The examiners will be on site in the workplace and in centers for the elderly. They will gather data on both enamel and root caries, periodontal diseases and other oral conditions. Not only do we expect this information to provide us with a much needed profile of oral health status, but we also expect some dividends from the survey process itself. It will help educate Americans, raise awareness to oral health and may even suggest new sites for dental health interventions: in the workplaces and centers. After all, part of the cost of dental care, now over $20 billion a year, involves time lost from work. Bringing care to the worksite could be a real bonus.

Basic studies of the pathology of the periodontal diseases con-

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tinue to rank high in research interest and activity today. One important approach is to trace the course of events in the oral cavity that leads to the colonization of the tissues around the teeth by periodontally destructive bacteria. Again, biotechnology methods have been fruitful in yielding a picture of how the bacteria found in the mouth interact to form mutually supportive clusters and colonies and provide a foothold by which virulent bacteria can take root and flourish, leading to the attack and destruction of oral tissues. A particularly virulent form of periodontal disease--localized juvenile periodontitis--affects young people. Recent studies of this disease suggest that there are genetic or familial factors involved and that the onset of this disease may depend on a coincidence of factors--hormonal changes occurring in adolescence, familial disposition, and the presence of the particular destructive bacteria. Further research should establish which individuals are at risk and can benefit from early detection of the disease and intervention by a vaccine.

One problem for dentists and patients alike is that the periodontal diseases are usually slow to develop; insidious infections can progress to the stage where deep pockets form around the teeth and the bone begins to resorb before the patient goes to the dentist. Scientists in our diagnostic laboratory are trying to remedy that situation by developing digitized x-ray techniques to permit early diagnosis. An added bonus of their new methods is that the radiation level required is less than a tenth that of a typical dental radiograph. We also expect to see improvements in oral hygiene approaches to the prevention of the periodontal diseases. New antimicrobials to be tested this year may turn out to be the ideal anti-plaque measure for eliminating the build-up of harmful bacteria above the gumline.

More advanced cases of periodontitis may require professional intervention to eliminate bacteria from deep pockets and in some cases, use of an antibiotic drug such as tetracycline. In addition to its bactericidal effects, tetracycline has been shown to inhibit the production of tissue collagenase--an enzyme that breaks down collagen, the basic building material of connective tissues, ligaments and bones. Tetracycline may also inhibit bone destruction.

One of the ironies of the periodontal diseases is that the body itself contributes to its own destruction through activities and products synthesized by cells of the immune system. Thus, these diseases share certain features with other inflammatory diseases such as rheumatoid arthritis. Because of these commonalities and because of a long history of pioneering research on the basic building materials of bones and teeth, NIDR scientists are among the major contributors to some of the most important studies today in immunology, in bone and joint diseases, and in the development, growth and repair of all tissues. In the past year, for example, workers in our mineralized tissue laboratory reported development of a new and easy method of isolating bone-forming cells from any patient for cell culture and study--a technique which should shed light on the pathology of several bone and joint diseases. One of the more exciting searches currently underway is for a particular substance, bone morphogenetic protein, that appears to be essential to bone growth and repair.

I have covered a few subjects in depth at the expense of many other areas that rank high on our agenda in both the quality and

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potential of research. Our researchers in salivary gland studies continue to unravel the intricacies of neural control over salivation. At the same time they have come up with a new treatment for dry mouth--an all too common side effect of drugs or a symptom of exocrine gland dysfunction in older patients. The new pain research unit in the NIH Clinical Center has expanded its studies and has had good results with the use of tricyclic antidepressant drugs in the treatment of diabetic neuropathies, post-shingles pain and atypical facial pain. Immunologists have added to our knowledge of AIDS through fundamental studies showing defects in monocytes, the white blood cells that are a major line of defense against infection.

I would be remiss if I did not mention several other areas where the NIDR is working to build partnerships, enhance its research potential, and address questions raised by this very Committee. In particular, you asked that we seek the broad consultation of the dental community in formulating plans for the use of the center mechanism in the future. We have taken your advice in letter and in spirit and have convened a 20-member panel consisting of representatives of the principal professional organizations, directors of eight of our existing centers, members of the National Dental Research Advisory Council and other appropriate persons. The panel has met twice and will meet again this spring. It has taken testimony and gathered a store of information provided by our staff and others to aid in their deliberations. We expect to provide this Committee with our conclusions based on the panel's efforts by this summer. These occasions have been important forums for discussion that will pay off in forging a more integrated, tightly knit community that will help shape a creative future for dental research.

On our part, and with that same stake in the future in mind, I am delighted to report that we were able to accelerate implementation and reviews of our new Dentist Scientist Award--a five-year program that allows graduating DDS or DMD candidates to learn clinical research skills, pursue basic biomedical studies, and engage in guided laboratory research. This will equip them with that unique combination of basic and clinical capabilities so necessary to facilitate advances in oral health research.

Lastly, let me mention that the ultimate concern of biomedical and behavioral research is the health of people. We, in dental research, started with a major focus on dental caries and young people and are now moving on to extend our research and resources to improving the oral and general health of all Americans. Further, we are increasingly turning our attention to the oral health of the elderly. Together with the National Institute on Aging and the Veterans Administration, we are collaborating on a project to develop a research agenda addressing the needs of this ever-growing segment of the population. These efforts reflect the growth of oral health research and the realization that the field cannot be narrow. Oral health and general health are inextricably linked, and we in dental research have much to contribute to and much to benefit from collegial collaboration. In the end the rewards will be improvements in the health, in the life span and in the quality of life of all Americans.

Mr. Chairman, the 1986 budget request for this Institute is $93,439,000, a decrease of $7,331,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's

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freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985 this Institute will fund 100 new and competing grants of which 14 will receive 3 years of support. In addition, we will fund 11 centers, of which 1 will receive 2 years of support.

Biography of Dr. Harald Löe

July 19, 1926, Steinkjer, Norway

Education: Oslo University, Norway, D.D.S., 1952; Dr. Odont, 1961.

Professional History: 1952-1955, Instructor in Operative Dentistry, School of Dentistry, Oslo University, Oslo. 1956-1962, Research Associate, Norwegian Institute for Dental Research, Oslo. 1957-1958, Fulbright Research Fellow and Research Associate, Department of Oral Pathology, University of Illinois, Chicago. 1959-1962, University Research Fellow, Oslo University, Oslo. 1960-1962, Associate Professor, Department of Periodontology, School of Dentistry, Oslo University, Oslo. 1966-1967, Visiting Professor of Periodontics, Hebrew University, Jerusalem. 1962-1972, Professor of Dentistry and Chairman, Department of Periodontology, Royal Dental College, Aarhus. 1971-1972, Associate Dean and Dean-elect, Royal Dental College, Aarhus. 1972-1974, Professor of Dentistry and Director of the Dental Research Institute, University of Michigan, Ann Arbor. 1974-1982, Dean and Professor of Periodontology, School of Dental Medicine, University of Connecticut, Farmington.

Professional Organizations: American Dental Association; American Association for the Advancement of Science; International Association for Dental Research, American Association for Dental Research; American Academy of Periodontology; Commission on Oral Health Research and Epidemiology, Federation Dentaire Internationale; World Health Organization's Oral Research Advisory Group; American College of Dentists, International Association for Dental Research Periodontal Research Group; American Association for Dental Research Periodontal Research Chapter; International College of Dentists; Danish Dental Association; Scandinavian Association for Dental Research; Sigma Xi, The Scientific Research Society.

Honors, Awards: honorary doctorate degrees from the University of Gothenburg, Sweden, 1973; the Royal Dental College, Denmark, 1980; University of Athens, Greece, 1980; the Catholic University of Leuven, Belgium, 1980; Georgetown University School of Dentistry, Washington, 1983; and the University of Lund, Sweden, 1983; Alfred C. Fones Medal for Outstanding Achievement in the Service of Humanity, 1984; International Award of the Friends of the University of Connecticut School of Dental Medicine, 1983; Lister Hill Memorial Lecturer, University of Alabama, 1983; Daniel F. Lynch Award, Dental Society of Greater Waterbury, 1983; International Lecturer of the Year Award, Academy of International Dental Studies, 1983; Gold Medal, University of Ghent, 1982; Centennial Award, University of California School of Dentistry, 1982; Award of Merit, Hartford Dental Society, 1982; Irving Glickman Memorial Lecture, Tufts University, 1979; William J. Gies Award, American Academy of Periodontology, 1978; Arthur Merritt Memorial Lecturer, Baylor University, 1977;

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Certificate of Achievement, Connecticut Society of Periodontists, 1976; Massachusetts Dental Society International Award, 1973; honored by Her Majesty the Queen of Denmark (Knight of Danebrog), 1972; American Society of Preventive Dentistry International Award, 1972; International Association for Dental Research Award for Basic Research in Periodontics, 1969; Aalborg Dental Society Prize of Honour, 1969; Erik Berg Foundation Prize of Honor, 1965; Ingv. Stokke Prize for Outstanding Dental Research, 1959; Norwegian Dental Association 75th Anniversary Prize, 1959; honorary memberships in several professional societies.

HERPES VACCINE

Senator WEICKER. This new herpes vaccine, is that already available to the public now?

Dr. LÖE. No; it is not. This is an experimental vaccine. It works in the rodent model. We will have to proceed through completion of animal studies and then on to a phase 1 trial.

Senator WEICKER. How long do you see this before it comes to the public?

Dr. LÖE. Well, that could happen within the next few years.

Senator WEICKER. If everything goes well?

Dr. LÖE. Right.

Senator WEICKER. How did the Dental Institute get into the matter of herpes?

Dr. LÖE. Well, it is really our domain. The cold sore and the fever blister have always been more prominent in the oral area than in——

Senator WEICKER [interposing]. I think when most people conceive of herpes they conceive of it in the genital area.

Dr. LÖE. In the last few years, yes. There are a variety of herpesviruses.

Senator WEICKER. I am being educated. I don't know this. That is what I am trying to find out.

Dr. LÖE. Both shingles——

Senator WEICKER [interpsoing]. Shingles is also a herpes disease?

Dr. LÖE. Yes; which is also found in the mouth. We have had a general interest in virology for many years.

Senator WEICKER. Whatever work you do, whatever findings you have, do those relate with, let's say, Dr. DeVita's Institute? Isn't there some connection of herpes and cancer?

Dr. LÖE. Yes; and more than that, this effort of moving basic virology research to the development of a vaccine or a vehicle for the immunizing agent was a collaborative effort with NIAID. We use the vaccine for smallpox as a vehicle for the herpes immunizing materials. So the NIDR is collaborating with the NIAID in one area and is collaborating with the NCI on the possible role of the herpesvirus in the cancer area. We share, of course, an interest here because both Institutes are concerned about oral cancers.

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NEW ANTIPLAQUE AGENTS

Senator WEICKER. What are these new toothpastes I hear about relative to plaque, et cetera? Can you give us a little insight?

Dr. LÖE. It is more than toothpastes. A research effort has been going on for the last 15 or 20 years to define and delineate the causes of periodontal and other diseases. We now know that the periodontal diseases are infectious diseases caused by microorganisms—bacteria that are usually found in the mouth, but grow to the point where they become pathogenic. If you have a bacterial infection in the mouth, the reasonable thing to do in this day and age is to combat it with an antibacterial agent. Up to now, we have had only mechanical means of controlling the growth of bacteria on the teeth and gums. What is happening at the moment is an appreciation that other measures can be used to control bacterial colonization of oral tissues. Now these antibacterial agents can be delivered through mouth rinses or dentifrices. With active agents against the target bacteria, we are getting additional means of controlling the periodontal diseases—besides standard mechanical methods, such as good tooth brushing and cleaning. These new developments could be quite important in terms of preventing these diseases.

NIDR GRANTS

Senator WEICKER. You have, what, the smallest Institute in terms of funding?

Dr. LÖE. Yes.

Senator WEICKER. Am I correct when I say your cut vis-a-vis continuing and competing grants will be somewhere near 23 percent?

Dr. LÖE. Yes; the competing grants will be reduced from 130 to 100 grants. We will have 86 new grants in 1985.

Senator WEICKER. How do you view that?

Dr. LÖE. Well, from a program point of view, we will see an increase in 1986 because we will be funding 43 more new grants than during 1985. So there is some program enhancement in the 1986 budget. However, our noncompeting grants will be reduced by 65. In terms of the 1985 appropriations we will be reduced by a total of 38 grants.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I thank you.

I have other questions, Dr. Löe, for response to the record. I thank you for the information you have given to us.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

OMB DIRECTIVE

Question: Dr. Löe, did you have an opportunity to respond to the OMB Directive at any time? If so, what is your response? If not, would you care to respond now?

Answer: Directives from OMB are answered at the NIH Director's level. However, all BID Directors are given the full opportunity through BID Directors' meetings and special meetings to discuss such directives and to express the impact they would have on their respective Institutes.

RESEARCH BUDGET

Question: Dr. Löe, the NIDR has one of the smallest research budgets at NIH. In the FY 1985 appropriation, Congress funded 130 new and continuing grants. The wizards at OMB propose a reduction of that number to 100, a 23% cut. As Director of NIDR, can you justify this cut? How can your Institute and the dental research community absorb such a large cut?

Answer. In structuring the 1986 President's budget, the main concern was to minimize the need for increases between 1985 and 1986. The 1985 current estimate budget will fund 5,000 new and competing research project grants at NIH. The NIDR's share of the 5,000 new and competing research project grants is 100 grants.

NIDR has and will continue to inform the dental research community of the short fall of new and continuing research project grants in 1985. This will entail funding fewer competing research project grants and terminating some of the Institute's competing renewal research project grants.

Question: What is the impact on ongoing research?

Answer: At this time, we cannot give a precise indication of the impact on ongoing research.

Question: Can you give us an example of a research project that will not be continued and tell us what may be lost? Can you give us an example of new research that may not receive funding, and estimate its long-term impact?

Answer: Possibilities for interim funding from other sources will be explored. Since the review process of all applications is not complete, it would be conjecture to give specific examples of unsupported research at this point.

LOST RESEARCH

Question: I note that in FY 1986 you will be supporting a total of 370 grants or 38 less than the FY 1985 appropriated level.

--What kinds of research will go unfunded?

--How many of these projects will be stopped in midstream by loss of continued support?

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Answer: Until after the May 1985 National Advisory Dental Research Council meeting, it will be inpossible to specify exactly which research activities will not be supported. The priority scores will be a critical factor in this determination.

HERPES VACCINE

Question: I understand that research supported by your Institute is close to developing a vaccine for herpes. Can you tell us about that and estimate the economic impact that vaccine may have over the long term?

Answer: The NIDR, in collaboration with the NIAID, has developed a vaccine against herpes simplex type 1 virus, the cause of cold sores or fever blisters. The vaccine is effective in mice against herpes type 1 infections and also produces substantial protection, again in mice, against infections by herpes type 2 virus, the cause of genital herpes. The results are very encouraging. Following some additional experiments in animals we will want to move on to clinical trials in human subjects. Based on a recent report prepared by the Institute of Medicine it was estimated that the cost to the American public of herpes type 1 and 2 disease amounts to $450 million a year. A successful vaccine could save up to $300 million a year.

BUDGET IMPACT

Question: You are asking for a budget that is $7+million less than in FY 1985. What is the overall impact of that loss in funding, and how will it affect the momentum of dental research? What specific program adjustments will have to be made? Are there any new avenues of promising research that will not be able to be followed because of lack of funding?

Answer: As with any budget, certain lower priority but nonetheless, promising useful areas of research will not be funded. For example, the 1986 budget will not permit funding new categorical or thematic research centers, nor will it allow us to admit new candidates to the Dentist Scientist Award program. In addition, it will not be possible to pursue clinical trials of an anti-caries vaccine (phase I); a clinical trial of an anti-herpes vaccine (phase I); and a trial of non-steroid anti-inflammatory agents in the control of pain. A variety of new avenues of promising research related to molecular biology will not be fully realized. Examples of such research include studies of the mechanisms of metastasis of cancer cells, basic research on bone biology and further analyses of the non-collagen components of tissue matrices.

DENTAL INSTITUTES

Question: Dr. Löe, what progress have you made in establishing your thematic centers for dental research, and have the problems with the dental institutes been solved? Now under the 1986 budget proposal, how many centers will you fund and what opportunities will you have to forego?

Answer: In 1984 three thematic centers focused on dental caries were initiated. At this time we have applications for two more types of thematic centers--for periodontal diseases research

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and for oral health and behavior research. Applications for these centers have been reviewed, and two applications for periodontal diseases research centers and one for an oral health and behavior research center have high scientific merit and have been approved with fundable priority scores. However, we will not be able to fund these centers under this budget proposal. In addition, we had announced a request for applications for a research center on orofacial pain and had intended to announce, in 1986, a request for applications for a research center focused on oral health problems in the elderly.

Regarding the dental institutes, the NIDR is in the process of developing a plan for the future direction of the centers program which will be submitted to Congress in August of this year. In the interim, the NIDR will maintain the existing five Dental Research Institutes at not less than their 1984 levels for the remainder of their approved program periods. In the case of the Dental Research Institutes at the University of Washington and at the University of North Carolina, support at the 1984 level is being extended through both 1985 and 1986 pending the recommendations concerning the use of large grant funding mechanisms growing out of the present consultation process.

Under the 1986 budget request a total of 11 centers will be supported during 1986, but only 10 center awards will be made from 1986 funds, since one center will have been funded for 2 years from the 1985 budget.

ADVANCES IN DENTISTRY

Question: You have made several optimistic pronouncements over the past two years with regard to emerging treatment technologies that would result in a marked reduction in dental disease. What has occurred over the past 12 months in this area?

Answer: We are seeing real progress in the development of new antibacterial and antiplaque agents which can go far to prevent the major dental diseases, both caries and the periodontal diseases. Some of these products should be available in the near future. Also, significant advances have occurred in vaccine development. Both caries and oral herpes vaccines have been tested in animals. Another area where we are advancing is in perfecting the intra-oral device for the slow release of fluoride into the oral cavity. This approach may be the treatment of choice for controlling tooth decay in handicapped, in immunocompromised individuals and other high risk groups. We have also seen marked progress in the professional application of dental sealants--synthetic coatings applied to the pits and fissures of teeth to seal out decay. The remarkable increase in use of the method follows a highly publicized Consensus Development Conference we co-sponsored at the NIH.

Question: I have been reading about genetic experiments relating to the cloning of enamel-producing cells. Can you explain how this will be brought to the patient?

Answer: The cloning of the genes that code for the enamel proteins constitutes the first step toward a molecular understanding of enamel formation. Once we have identified the gene and gene products involved in their regulation, we will be able to move on to experiments to synthesize enamel.

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Question: What kind of progress has been made in techniques for pain killing?

Answer: NIDR scientists have been achieving good results through the use of tricyclic antidepressants in treating the intense chronic pain following attacks of shingles--"post-herpetic neuralgia." Further, a combination of a long-lasting anesthetic and a non-steroidal anti-inflammatory agent has been found to be effective in controlling post-operative dental pain.

Question: What is the effect of the proposed FY 1986 budget on these new developments?

Answer: The effect of the 1986 budget will be the slowing of progress in these areas. We will defer large scale trials of the anti-caries and herpes vaccines and a trial of non-steroidal anti-inflammatory agents to control pain. We will also delay funding for an orofacial pain center.

PAIN RESEARCH

Question: Doctor, your Institute has a strong interest in pain research. What are you doing about technology transfer in this area?

Answer: The NIDR will hold a Consensus Development Conference entitled "Anesthesia and Sedation in the Dental Office" on April 22-24, 1985. The conference is co-sponsored with the Food and Drug Administration and the NIH Office of Medical Applications of Research. An expert panel will review the array of agents and approaches now available to dental practitioners for managing acute and post-operative dental pain. Results from the conference will be widely disseminated to professionals and to the general public and should yield important improvements in the efficacy and safety of pain control measures in the dental office.

A research conference on temporomandibular joint (TMJ) disorders is planned for late in FY 1986. It is expected to communicate much-needed information on the causes, methods of diagnosis, and treatments of TMJ disorders.

The NIDR is the lead agency for the Pain Research Unit in the Ambulatory Care Research Facility of the Warren G. Magnuson Clinical Center on the NIH campus. This unit sees patients referred from other NIH components and from physicians in the community at large. It serves as a focus for research and research training on all aspects of acute and chronic pain, not limited to the orofacial region but in any part of the body, thus serving as an important vehicle for conducting research and communicating findings on pain assessment, diagnosis, and new forms of treatment.

In addition, NIDR intramural scientists and grantees have been active in communicating directly through the NIH-sponsored Medicine for the Layman lectures, radio question-and-answer shows, other media interviews, and as officers and spokesmen involved in the information liaison activities of the major research societies in this area, the International Association for the Study of Pain and the American Pain Society.

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BIOMEDICAL RESEARCH

Question: Dr. Löe, Your Institute is one of the smaller institutes at NIH but has been responsible for some very good research that has impacted upon biomedicine as a whole. Do the scientists supported by NIDR receive the same chance for funded research as those supported by the larger, well-funded institutes?

Answer: Actually, scientists supported by the NIDR have somewhat greater opportunities to gain research support because our award rate is higher than other Institutes.

Question: What are some of the research findings that were funded by NIDR that became useful to other areas of biomedical research?

Answer: NIDR-supported scientists study all the tissues of the oral cavity--unique organs like the teeth or the taste buds--as well as the salivary glands or the bones of the jaw which are similar to other body tissues. Thus how the oral tissues behave under normal and abnormal conditions has applications to the body as a whole. The oral tissues are also affected by systemic disease or general physiological changes, so that they can often serve as convenient models for study.

In the the case of AIDS, for example, diseases of the mouth--ranging from viral infections to Kaposi's sarcoma lesions--are often the first signs of the disease. Dental scientists have now identified specific defects in immune cells, in both monocytes and lymphocytes, that contribute to the weakened defenses against infection so characteristic of AIDS. They are also working with NCI and NIAID investigators to develop a clearer clinical picture of the disease, noting, for example, a high incidence of S. Typhimurium, bacteria that cause gastrointestinal disorders in AIDS patients.

In arthritis, dental research investigators have been contributing fundamental insights concerning the structure and function of large molecules found in the ground substance of bones and joints. One group of molecules, the proteoglycans, normally act as shock-absorbers in joints. Defects in the structure of these molecules are now thought to be responsible for some forms of arthritis. In other arthritis research, dental scientists have noted differences in immune responses and other biochemical distinctions among rheumatoid arthritis patients that suggest that the condition is really a group of disorders that share common features.

The work on arthritis overlaps several areas of activity of dental research: immunology; genetics and molecular biology; and mineralized tissue studies. Investigators in these areas are studying the development of oral tissues at the genetic and molecular level and are using this knowledge to further understanding of a variety of diseases of collagen, bones and teeth such as Paget's disease, osteogenesis imperfecta and hereditary dwarfism. NIDR scientists have also identified naturally produced body chemicals that accelerate and improve the quality of wound healing, as well as a substance that can induce new bone formation. Intense efforts are being made to isolate and purify this substance, called bone morphogenetic protein.

Studies of cystic fibrosis are another example of how dental research is being applied to biomedicine as a whole. This genetic

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disease involves dysfunction of the body's exocrine glands, including the salivary glands. These glands are easily accessible oral tissues that dental scientists are now using to elucidate the basic genetic defect of the disease. Fundamental studies of nervous system regulation of the salivary glands and of water, electrolyte and protein transport are also areas where dental researchers are making discoveries relevant to all exocrine gland function, as well as suggesting particular defects in cystic fibrosis.

Diabetes is another systemic disease where dental research has made important discoveries. The significance of viruses in the etiology of diabetes has been identified. The suggestion is that viral infection may trigger an autoimmune response in which the body's defense cells attack insulin-producing beta cells in the pancreas. Clinically, dental investigators have collaborated on studies that have identified a triad of genetic markers that will predict whether a child in a diabetic family is likely to develop insulin-dependent diabetes.

Other examples of how dental research findings have been applied to biomedicine include studies of pain perception and mechanisms of pain control; the development of animal models of herpes and a new experimental anti-herpes vaccine, as well as research that is showing the relationship between herpes (and other viral infections) with cell transformations associated with cancer; research in developmental biology that has identified risk factors for the development of cleft lip, cleft palate and other anomalies, such as excessive use of alcohol and antiepileptic drugs. Studies in microbiology are detailing the sequence of events and interactions between bacteria and the immune system that lead to the establishment of an infection and trigger inflammatory responses.

DENTIST SCIENTIST AWARD PROGRAM

Question: I understand that you are beginning to implement the Dentist Scientist Award Program. Could you briefly describe that program and tell us what the response has been from the dental community?

Answer: The response of the research community has been enthusiastic. We received over 100 inquiries about the program prior to the first receipt date, October 1, 1984. The NIDR subsequently reviewed 10 applications from institutions and 5 from individuals. From the first round of applications the NIDR plans to make 2 awards to individuals and 4 to institutions. By the time of the second receipt date we had received an additional 200 inquiries and we will be reviewing 8 institutional and 1 individual application.

The Dentist Scientist Award was conceived as a program that would answer a specific need for dentist scholars -- graduates with a DDS or DMD degree who would like to pursue careers in oral health research. Such investigators are essential in carrying out clinical research using state of the art and scientific methodologies facilitating the transfer of research findings from the laboratory to dental practice for the ultimate benefit of the public. The Award provides participates with 5 years of intensive preparation. During that time candidates acquire 1) the academic background and laboratory experience that are the equivalent of a Ph.D degree in a biomedical and behavioral science field; 2) advanced study in one of the clinical

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spec. lities of dentistry or an equivalent; and 3) individual experience in conducting original laboratory research. Individual awards are open to candidates holding a dental degree who are U.S. citizens or non-citizen nationals of the U.S. Applicants must be nominated by a qualified American university or professional school. Institutional awards are made to schools with strong well-established research and training programs, with the selection of candidates deferred to the school's program director. Each Dentist Scientist Award is a five year, nonrenewable grant. Compensation is based on the salary scale of the institution. It is expected that a candidate's salary will increase over the period of the award, but at no time can it exceed $40,000 a year. A maximum of $75,000 for research support will also be available for the candidate over the five-year period.

Question: How much money will be invested in this program in FY 1986?

Answer: In 1985 the NIDR will invest $1.5 million to support roughly 5 individual and 6 institutional awards in the Dentist Scientist program and a parallel program, the Physician Scientist Award for Dentists. This is the same amount we plan to invest in 1986. This will allow us to support a total of between 25 and 30 participants in both programs.

CURRENT SERVICES BUDGET

Question: How much additional funds would be necessary in FY 1986 to maintain the same program level supplied by the appropriated FY 1985 budget?

Answer: To maintain the same program level in 1986, the NIDR would require $2,037,000 in additional funds above the request. If we were to maintain current services the NIDR would require $10,816,000.

FLUORIDATION

Question: I understand that fluoridation of public drinking water is an effective way of preventing dental decay. Yet opposition is still being heard. Is there any compelling data that fluoridation can result in adverse health effects, including cancer?

Answer: No adverse effects of community water fluoridation have been found in human beings. Careful and very extensive epidemiological studies show no increase in cancer rates in areas with fluoridated water. This is in agreement with experiments which indicate that fluoride, at levels used for the prevention of dental diseases, is not mutagenic and does not harm DNA.

FUTURE OF DENTAL RESEARCH

Question: If demand for dental care in the public sector decreases because of better overall dental health, how will that trend impact on NIDR in coming years?

Answer: The oral health of Americans is improving and the NIDR is proud of the role it has played in that improvement. However, much remains to be accomplished. In spite of the reduction in dental

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caries in children, the disease has not been eliminated. Nearly two-thirds of American children still experience decay. Our most recent survey (1979-1980) indicated that by age 17 the average number of caries lesions was 11. For high-risk children, decay can attack every tooth in the mouth.

The situation in the adult population is not clear. Some adults are enjoying good oral health because their teeth have benefited from exposure to fluoridated water during development and because they practice good oral hygiene. Other adults, certainly older aged groups, have lost teeth due to decay or to the periodontal diseases. Because we are not certain of the oral health status of mature Americans we are conducting a major national oral health survey.

Today, we have a far better understanding of caries and the periodontal diseases and we are developing superior methods of preventing these diseases. But even if these new approaches were available and widely adopted there would still be groups of Americans with unmet needs. Only about half the population sees a dentist in the course of a year. There would still be high-risk groups: the handicapped, the immunocompromised, and other individuals with disease or disability who require special approaches. Moreover, the research on dental caries that has led to improved tooth survival in young people may place more teeth at risk for the periodontal diseases later on, or for a form of decay that affects the roots of teeth, if these surfaces become exposed as a result of gum recession. Thus, we expect to expand research on oral health problems in adults and in the elderly -- at a time when these groups represent an ever-increasing proportion of the population.

In addition, there remain important reseach questions concerning caries and the periodontal diseases, as well as other areas of research supported by the NIDR that go beyond diseases of teeth and gums.

We believe findings from research in these areas will expand the profession of dentistry. Such research includes studies of oral cancers and of soft tissue diseases such as herpes and papilloma virus infections. It includes the need for research to understand and prevent congenital craniofacial anomalies; to find better treatments of orofacial trauma; and to improve methods of orthodontic correction and tooth implants. We need better diagnoses and treatments for chronic orofacial pain and salivary gland dysfunction, and for a host of other problems affecting oral soft and hard tissues. In short, the NIDR research agenda will remain broad and full for years to come.

Question: What do you feel will be the long-range economic impact of NIDR-sponsored research and of better dental health?

Answer: The economic impact of NIDR-sponsored research can already be measured in terms of the improved oral health of U.S. school children aged 5 to 17. Based on surveys conducted in 1971-74 and in 1979-80, the caries prevalence in school children has declined by over a third, and a third of school children in 1979-80 were completely caries-free. It has been estimated that the results of this decline in 1981 alone meant a savings of $2 billion in the nation's annual dental bill for that year, estimated to be $20

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billion. Significantly, that $2 billion is twice the total budget that has been allotted to the NIDR over the course of its 37-year history.

At present, dental diseases rank second in total direct costs of the 13 leading health problems in the nation. Also, the U.S. National Health Interview Survey reported that in 1981, 4.87 million dental conditions caused 17.7 million days of restricted activity; 6.73 million days of bed disability; and 7.05 million days of work loss. There is every reason to believe that the results of NIDR-sponsored research in the long run will continue to lead to improved dental health for the U.S. population, lower expenditures for dental treatment, and lead to less disability and work loss time.

Question: What plans do you have to accelerate dental research for special populations like the elderly and disabled -- both of which categories will increase as our population ages?

Answer: In July 1984 a collaborative project involving the NIDR, the NIA and the Veterans Administration was initiated to address the health needs of the elderly. We expect this activity to yield: 1) a research agenda; 2) a catalogue of relevant resources and activities of the three organizations; and 3) an implementation plan for cooperative activities. These documents would be widely disseminated to the research community to stimulate research projects relevant to the elderly in areas such as epidemiology, disease prevention, nutrition and behavior science, and to encourage research training in this important area.

The primary emphasis of three new Dental Caries Centers, initiated in 1984, is root caries, a dental problem of adults and the elderly. The findings from a variety of ongoing research projects should also benefit the elderly: studies of the effects of fluoride mouthrinsing on the prevention of caries in adults; an adult oral health survey which includes documenting the oral health status of the elderly who frequent senior centers; the development of new and improved dental materials; research on implants; and investigations to improve the tissue base for prosthetic appliances.

In terms of the disabled, the development of the intra-oral device for the slow release of fluoride represents a major means of controlling caries. The antimicrobial and anti-plaque agents under development will also be important aids to preventing tooth decay and periodontal diseases in the disabled.

INFORMATION TRANSFER

Question: Can you bring the Committee up to date on what progress is being made to bring research advances to the practicing dentist? Can more be done to increase information flow to the practicing dental community?

Answer: The NIDR maintains a modest but vigorous health promotion/science transfer activity. Indeed, the fulfillment of our goal of improving the oral health of the nation depends in large part on the effective transfer of research results to other scientists, health care providers, and the general public. Activities that we support in this area include: publishing the results of research in professional journals; sponsoring or co-sponsoring conferences and

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workshops; publishing and distributing the proceedings of meetings; participating in professional meetings; and visiting dental schools. In addition, the NIDR has supported the production of educational films for practitioners and the development of educational materials for use by practitioners with the general public. These efforts are directed at dental practitioners, educators, and students.

We are investigating what can be done to increase information flow in all these areas, within available resources.

PREVENTIVE RESEARCH

Question: In a speech before the American Pharmaceutical Association, Dr. Wyngaarden said that 28% of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: The ultimate aim of NIDR-sponsored research is the prevention of oral diseases and disorders. Prevention research includes studies to elucidate the role of genetics and of environmental agents in heightening the risk of congenital craniofacial anomalies. Prevention research also includes the development of antiplaque and antimicrobial compounds to prevent the periodontal diseases and dental caries; the development of vaccines against herpes simplex virus infection; and the delineation of strategies to improve the acceptance and use of disease-preventive methods by the public and by the profession.

Question: What percent of your budget is directed to preventive research?

Answer: In 1984 approximately 24 percent of NIDR obligations (grants, contracts, and intramural research) was directed to prevention research. About the same percentage will apply in 1985 and 1986.

Question: How are the results of this research being translated into useful public information?

Answer: The results of this research are translated to useful public information through such activities as Consensus Development Conferences -- for example, the conference on the use of Dental Sealants to Prevent Tooth Decay held in December, 1983 and through films, pamphlets, and articles for lay media. A good example of research that has moved from basic studies through the adoption of a public health measure for the benefit of the consumer has been the demonstration of the role of fluorides in the reduction of tooth decay.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: The NIDR developed an Operational Goals Planning process as part of an organizational realignment undertaken in 1983. This effort, involving input from all groups of employees, was designed to enhance employee morale and achieve the highest possible

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efficiency as administrative overhead was reduced. Every employee in the Institute had an opportunity to participate in more than one session intended to elicit suggestions, concerns and problems. The high degree of employee participation has resulted in an effective Operational Goals process, improved morale, and improved communication across all levels of the organization.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: The NIH has a study in progress to identify factors which contribute to the unit time differences between BIDs. These data will provide the BIDs with quantifiable data which can be used to take management actions, individually or collectively, to reduce unit time.

Question: What changes in procedures have you initiated recently to decrease administrative costs?

Answer: The NIDR has recently reorganized its extramural programs, consolidating program activities from six areas to two. This consolidation has reduced the required staff from 36 to 30.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: The NIDR has increased its staff in the scientific review area to ensure the equitable and complete review of research proposals; this is essential to the review process.

PROMISING AREAS OF RESEARCH

Question: Doctor, last year your institute developed a five year plan. That plan identified promising areas of research. Briefly indentify some of those areas and tell us whether or not you will be able to pursue them with this budget request.

Answer: The NIDR Long-Range Research Plan, Challenges for the Eighties, identified research objectives in 14 major areas related to oral health. These include studies of diseases, craniofacial anomalies, orofacial pain and soft tissue diseases. In addition, research on salivary glands, mineralized tissues, nutrition, behavioral studies, restorative materials, and implants was emphasized. Several cross-cutting issues were identified, as well as strategies to accelerate research progress. These included the creation of categorical and thematic research centers, an approach that facilitates multidisciplinary and interdisciplinary research. Three such centers planned for funding in 1986 cannot be initiated. Two of these centers were to focus on periodontal diseases--especially in research on diagnosis and treatment of these diseases. A third research center was to focus on oral health and behavior. In addition, we had announced a request for applications for a new research center on orofacial pain which will also be deferred.

The 1986 budget request will also curtail new admissions to the NIDR Dentist Scientist Award program. This program will assist in the development of dental clinical investigators with skills

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essential to carrying out the recommendations of the NIDR Long-Range Research Plan. Also, several clinical trials will not be initiated. These include trials of an anti-caries vaccine (phase I); and a trial of non-steroid anti-inflammatory agents in the control of pain.

COMPREHENSIVE STUDY OF CENTERS PROGRAM

Question: We are aware that you have undertaken a comprehensive study of your centers program. Tell us how you are involving the dental research community--and especially the 5 Dental Research Institutes--in this process.

Answer: Following discussion with the National Advisory Dental Research Council, a 20-member ad hoc Consultant Panel was appointed to provide oversight and guidance. Members of this Panel include all five Directors of the Dental Research Institutes and three Directors of NIDR specialized research centers. The group also includes representatives of the American Association of Dental Research, the American Dental Association, the American Association of Dental Schools and members of various NIDR advisory and consultant bodies. The Panel has met several times including a special session in January devoted to taking testimony from Directors of large grant programs (either program projects or research centers) or their representatives. The Panel has been briefed by NIDR and other NIH staff on the kinds of research funding mechanisms used to support research and on how individual components of the NIH vary in their use of these mechanisms. In addition to scheduled meetings of the Ad Hoc Consultant Panel, a discussion of the use of centers and other funding mechanisms has been included in other NIDR activities that engage broad segments of the dental community, such as a meeting of dental deans held on the NIH campus in February. Letters have also been sent to some 800 research scientists or concerned organizations inviting their comments in writing or their attendance at center discussion sessions held in conjunction with the annual meetings of the major professional societies, such as the American Association of Dental Schools and the American Association for Dental Research.

We feel that the existence of the Panel, the number of meetings it is holding, and the discussions aired at meetings that draw broad segments of the dental community ensure that the discussions of centers as well as other funding mechanisms to support oral health research are receiving the widespread consultation and participation requested by the Committee.

Question: When will you have a final report on the future direction of the centers program?

Answer: The NIDR will submit its report to Congress in August of this year.

HERPES RESEARCH

Question: We understand that your Institute has played a major role in the development of a vaccine which shows protection in animals against herpes virus #1 and herpes virus #2. What are the next stages of this research? Is there enough money in your budget to carry out the next stages of this vaccine research?

Answer: NIDR, in collaboration with NIAID, has developed a

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vaccine against herpes simplex virus using recombinant DNA technology. The vaccine is effective in mice against herpes type 1 and also produces substantial protection against herpes type 2 in these same animals. The results are very encouraging, but some additional experiments must be carried out in animals. The current budget request does not provide for clinical trials in human patients.

Questions Submitted by Senator William Proxmire

CARIOGENICITY OF FOODS

Question: What is the current status of research into predicting the cariogenicity of foods?

Answer: This research has concentrated on the development of in vitro, animal, and short-tem human tests of the cariogenicity of foods. Examples of tests now available include the use of intraoral microelectrodes to detect the acid production of foods eaten by human volunteers and a highly controlled method for conducting feeding experiments in laboratory rats. These techniques cannot unequivocally determine that a food will be cariogenic in human beings since cariogenicity depends primarily on how frequently the food is eaten. Nevertheless, the tests, especially when used in combination, can help detect foods with high and low cariogenic potential in the human diet.

Question: Do you think that some day it will be possible to label foods in such a way as to promote good dental health?

Answer: Yes, I think it will be possible. In fact, such a system has been in use for years in Switzerland

Question: I understand that a Foods, Nutrition and Dental Health Program, functioning under the auspices of the American Dental Association, was established in 1978 to promote research into the relative cariogenicity of foods--the tendency of foods to promote tooth decay. Apparently the program is in the process of developing support for industry labeling that would promote certain foods as "dentally improved." Do you believe it is possible to make that claim at this point, given the status of your research into cariogenicity?

Answer: Using the methods already mentioned, it should be possible to identify foods with little of no cariogenic potential. These could be promoted as "dentally improved" or some similar designation. However, more sensitive methods would be needed to discriminate among degrees of potential cariogenicity, and research is in progress to develop these methods.

ARTHRITIS

Question: Dr. Löe, on page five of your prepared statement, you talk about the fact that tetracycline has been shown to inhibit the production of an enzyme that breaks down the basic building material of connective tissues, ligaments and bones in periodontal diseases. On the next page you point out that periodontal diseases share certain features with other inflammatory diseases such as

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rheumatoid arthritis. These comments would suggest that the treatment of rheumatoid arthritis with tetracycline, a treatment that has been the subject of great controversy over the past few years, might make sense. Is your Institute pursuing this line of inquiry on its own or in conjunction with the Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases?

Answer: NIDR-supported grantees have shown that tetracycline inhibits tissue production of collagenase, the enzyme that breaks down collagen, the basic building material of connective tissue, ligaments and bones. This activity, combined with the antibiotic action of the drug, makes it useful for short-term adjunctive treatment of periodontal diseases -- which are bacterial infections. It is possible that tetracycline may be of use in other inflammatory diseases such as rheumatoid arthritis. At present, however, the NIDR is pursuing tetracycline studies on its own and primarily in relation to the periodontal diseases.

SPECIALIZED CENTERS

Question: In last year's budget submission you proposed obligating $5,702,000 for the work of seven specialized research centers. You are now planning to cut that budget to $4,594,000 and would fund only six centers in 1985. I can understand the administration's attempt to vitiate Congressional add-ons but here is one case where you plan to cut below your original budget. Can you tell us why you decided to undermine your own 1985 budget proposal? Are there any other cases where you are cutting back on your original submission?

Answer: It is a question of not initiating a new center rather than dropping an existing center. In the original 1985 budget we were hoping to add a 12th center to our total. Under the Current Estimate we were restricted to funding only the existing 11 centers (the five DRIC's, 3 specialized periodontal research centers, and three new caries centers initiated in FY 1984). The Institute was further instructed to use FY 1985 funds to support one of the 11 centers it currently supports for 2 years. Thus the FY 86 budget lists only 10 centers when in fact we are continuing to support all 11 existing centers.

COMPLIANCE AREA

Question: During the public witness hearings last year, it was quite evident that compliance per se is one of the major problems facing our nation's dentists today. Accordingly, the Committee would appreciate learning of the extent to which NIDR plans to fund research efforts in the compliance area and, in particular, the extent to which behavioral programs will be sought out.

Answer: The National Institute of Dental Research is currently funding 1.3 million in research grants focusing upon compliance with preventive or therapeutic regimens. Of this total $612,175 relates directly to enhancing patient compliance and the remaining $511,550 focuses upon improving the adoption of effective preventive regimens by health practitioners for the benefit of their patients.

Additionally, an announcement released during FY 84 requested applications for the establishment of Oral Health and Behavior Research Centers. A major objective stated in this RFA was to

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"Develop behaviorally-based interventions aimed toward establishing ... sustained adherence to preventive or therapeutic regimens." Eight applications received in response to this initiative will be presented to the National Advisory Dental Research Council in May, 1985.

CORPORATE CONTRIBUTIONS

Question: We understand an application for funding may be submitted by a Food, Nutrition and Dental Health program that functions under the auspices of the American Dental Association, but also receives corporate support. Does your Institute follow any general guidelines with respect to awarding grant funds to entities supported in large part by corporate contributions?

Answer: Grants are awarded by NIDR based upon the project's scientific merit and program relevance. As for all NIH grants, eligible investigators can be employed in non-for-profit and for-profit institutions.

SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until tomorrow, March 20, we will meet here again at 8:30 a.m. At that time we will hear from the following Institutes: the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases; National Institute of Neurological and Communicative Disorders and Stroke; National Institute of General Medical Sciences; and the National Institute of Child Health and Human Development.

The subcommittee will stand in recess until 8:30 tomorrow morning.

[Whereupon, at 11:58 a.m., Tuesday, March 19, the subcommittee was recessed, to reconvene at 8:30 a.m., Wednesday, March 20.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

WEDNESDAY, MARCH 20, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 8:35 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

STATEMENT OF DR. MORTIMER B. LIPSETT, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

L. EARL LAURENCE, EXECUTIVE DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS, DIABETES, AND DIGESTIVE AND KIDNEY DISEASES

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator WEICKER. The subcommittee will come to order. Today, we open our second day of hearings on the budget request for the National Institutes of Health.

We will hear first from Dr. Mortimer Lipsett, who is the new Director of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. This Institute conducts and supports research on diseases whose economic impact exceeds $100 billion annually. The NIADDK is requesting a fiscal year 1986 appropriation of $520 million, which is $24 million, or almost 5 percent, less than the amount appropriated in fiscal year 1985.

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Dr. Lipsett, welcome, and you may begin.

NUTRITION

Dr. LIPSETT. Thank you, Senator Weicker. It is a pleasure to appear before you, sir. You have my written testimony, and I thought that I would depart from that and tell you about some initiatives that we have in our four divisions, pointing out some of the important areas.

First there is nutrition. You are aware that we had a recent consensus conference on obesity which is a major problem for the American people, and it is certainly an important part of our mission. Obesity is a risk factor for a number of diseases, as you know, such as heart disease, some cancers, gallbladder disease, and arthritis, so that it remains a major problem for us.

Nutrition is also important in the digestive disease area with respect to peptic ulcers, colitis, and the role of fiber. Fiber is still ill-defined. Some fiber slows the uptake of sugar and may make control of diabetes easier. There is a role in gastrointestinal functions, and fiber may make a number of trace elements unavailable for absorption. So this is a major area of nutrition for study.

In kidney disease, there is a major trial going on right now, which is concerned with preventing or slowing the progression of chronic renal disease, to keep patients from getting to the point where they need dialysis and kidney transplantation. Here we are looking at the nutritional aspects of kidney disease in the hope that a protein diet, perhaps supplemented with a particular type of amino acid, will have a salutary effect.

Another area of nutrition is total elemental nutrition. We continue to learn more and more about the trace elements involved.

Another very large area where nutrition is prominent is osteoporosis. We need to be able to make recommendations on calcium intake, when women should start calcium supplementation, the role of fluoride, and the role of a number of trace elements. We will continue to push work in this area, and we are doing that in collaboration with the National Institute on Aging, which also has major research interests in osteoporosis.

TRANSPLANTATION

Transplantation is a second area I wish to touch on. I am sure Dr. Fauci will tell you of the very basic studies in transplantation immunology. We build upon those studies, and in a sense we are doing practical immunology with respect to transplantation.

Transplantation, again, goes across our four divisions. We have the transplantation of bones, and this is just getting underway, and of bone marrow for particular genetic diseases.

The committee is familiar with kidney transplants. We have a trial that will be getting underway shortly in cooperation with NIAID in which we will be looking at the elements of the kidney that cause rejection of the transplant and attempting to overcome them. NIAID will develop the antibodies and participate wi[illegible] clinical trial.

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The transplantation of liver poses continuing problems not only in finding the livers but in maintaining them in a reasonable state until they can be transplanted. These studies are supported by NIADDK.

The pancreas is another area of great interest. Let me just mention that the first transplants of pancreatic islet cells have taken place during the past few months. Over the next few months to a year, we will find out whether these transplants continue to produce insulin and function normally. If this happens, we will then have to expand our efforts to make pancreases available to the investigators. We then will have to see whether this can be done in the nonimmuno suppressed patient. We have good reason to believe that this is possible from animal studies.

ENDOCRINOLOGY

The third broad area is what I might call "how cells talk to each other," that is what we called endocrinology 10 to 20 years ago. I will mention just a few places where this is important. In the major form of diabetes, adult diabetes or type II diabetes, we need to know why the islet cells don't secrete enough insulin in response to appropriate signals. This is an area of great importance since there are about 11 million type II diabetics.

In the gut and in the brain, there are a variety of small peptides or small proteins, if you will, that have been identified, and some of these peptides can be dignified as hormones. They regulate motility. They affect appetite and satiety and affect secretion. You can see that the movement in gastrointestinal disease research is very much in this area of cell communication.

With respect to cell communication, we need to know how hormones affect the cells in the bones. We are giving estrogen to postmenopausal women now, but we don't know about a variety of hormones, new and old that modulate bone growth.

Finally, new messengers have been identified such as bone morphogenic protein which stimulates growth in new bone, and bone growth factors. These are brand new findings that, obviously, have great potential in the future for treatment, presumably, of osteoporosis, and perhaps many other bone diseases.

Then in all of the institutes, there have been many substances identified that act on particular white cells. These interleukins and other agents carry important information in rhumatoid arthritis and osteoarthritis. Again, this is the problem of one cell communicating with another in a way that promotes disease.

CELL BIOLOGY

The final area is that of cell biology, a familiar concept to you. Let me just point out how that sweeps through all of our divisions.

We have a very large investment, both extramurally and intramurally, in studies of the process of secretion, and this is important in diseases such as cystic fibrosis, and in understanding how the adrenal gland works with respect to adrenaline secretion and how the pancreas secretes its hormones and enzymes.

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In cell biology, we use gene cloning, and have been successful in cloning genes for growth hormone and insulin. As a result and with considerable development work by industry, one is on the market, and the other will be soon. Our scientists have cloned the genes for various types of collagen which is important particularly in the skin, in the bone, and in various types of arthritis. For example, we have identified a particular type of collagen which is defective in osteogenesis imperfecta.

I would call your attention to erythropoietin, which is a hormone that stimulates the red cells to multiply and keeps the red cell level adequate in the blood. This material now has been cloned and is being prepared by DNA recombinant techniques. It will be available for treatment and diagnosis, and this opens new vistas in the area of particular blood diseases.

These are some of the very large cross-cutting disciplines in our Institute. I think that perhaps they illustrate better than anything else the depth of our commitment to both basic science on the one hand, and clinical science on the other.

Thank you, Mr. Chairman.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. We will insert your statement in the record before I ask you some questions.

[The statement follows:]

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STATEMENT OF DR. MORTIMER B. LIPSETT

As the new Director of this Institute, I appreciate the opportunity to describe several research achievements of our extramural grantees and intramural scientists, and to share with you some of our plans for the coming year. The research responsibility of this Institute is extensive, including arthritis, musculoskeletal and skin diseases; diabetes, endocrine and metabolic diseases; digestive diseases and nutritional disorders; and kidney, urologic and blood diseases. Collectively, these diseases pose an enormous health care burden, because of their widespread prevalence and relentless debilitating effects.

Arthritis, Musculoskeletal and Skin Diseases: Arthritis and related bone diseases afflict nearly 44 million Americans. The importance of arthritis is being recognized by a Secretarial initiative that will feature increased research on rheumatoid arthritis, osteoarthritis, and osteoporosis.

Research on the many forms of arthritis has moved rapidly within the past few years. One promising research area is the possible infectious etiology of rheumatoid arthritis. A particular type of small virus--designated "RA-1"--has been reported in joint specimens of several rheumatoid arthritis patients. Studies have also linked the Epstein-Barr virus with this disease. An intensive study of infectious agents in arthritis is being developed.

In other work, investigators have identified a nerve cell transmitter that induces pain and promotes inflammation in animals with a type of experimental rheumatoid arthritis. Aiding rheumatoid arthritis research is the development of a new animal model, the MRL/1 mouse, in which the disease arises spontaneously. This model mimics rheumatoid arthritis in humans and presents a unique opportunity to observe temporal development of the disease. Studies in this model suggest that proliferation of synovial lining cells may be the initial lesion in rheumatoid arthritis.

Research has also dispelled two common misconceptions about osteoarthritis: first, that it is an inevitable consequence of aging, and second, that it is necessarily caused by wear and tear in professional athletics, strenuous exercise or other physical stress. We now know that neither of these views is borne out by biochemical, clinical or epidemiologic data. In fact, we have learned that there are many modulating influences on the reaction of cartilage in osteoarthritis. Recently identified new protein factors, such as catabolin and

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mononuclear cell factor, may be responsible for the abnormal behavior of cartilage cells.

Osteoporosis is a disease that plagues older women particularly and costs this nation at least $3.8 billion annually. This Institute sponsored a Consensus Conference on Osteoporosis last year and supports a variety of small clinical trials and other studies to determine the best methods of preventing bone loss and inducing growth of new bone. Through these studies, we are learning more about calcium metabolism and have identified several new biochemical factors that promote bone growth--factors that look extremely promising as potential therapies for osteoporosis. We plan to intensify efforts in osteoporosis and other bone diseases, such as osteogenesis imperfecta, and are working closely with the orthopedic community to stimulate new research and to develop an intramural orthopedics program.

As with osteoporosis, systemic lupus erythematosus is particularly prevalent among women--striking them nine times more frequently than it does men. Research studies have demonstrated that early treatment of this disease may help to prevent or mitigate the devastating kidney disease often associated with lupus. Several of our intramural scientists have just reported important new findings regarding the clinical management of lupus; that is, that cytotoxic drug treatment retards the progression of failure of the kidney in patients with lupus nephritis.

I am also pleased to report that skin diseases research is proceeding with great momentum and vigor. We are developing enormously useful immunologic tools to characterize proteins in the skin, to help us understand the relationship between the outer and interior layers of the skin, and to pinpoint the defects present in such blistering diseases as pemphigus and epidermolysis bullosa. We have received an excellent response to our recently issued solicitation for increased research on epidermolysis bullosa and the biology of the skin's basement membrane zone. We are also in the process of establishing a patient registry to further research on this devastating genetic skin disease in children.

In psoriasis, recent studies have shown that normal skin from psoriatic patients exhibits abnormal changes when grafted onto immunologically deficient mice. This research suggests that the disease is not localized to psoriatic

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lesions. It also provides an important new model for studying the underlying disease process in psoriasis and possibly other skin conditions, such as ichthyosis, which shares in common with psoriasis, deranged keratin formation and accelerated epidermal cell turnover.

Diabetes, Endocrinology and Metabolic Diseases: Research in diabetes has brought remarkable advances in understanding and treating one of this nation's most serious public health problems--a disease that affects an estimated 11 million Americans at an annual cost of $14 billion. Fundamental research studies are helping to pinpoint the precise roles of genetic factors, the body's immune defense mechanisms, and environmental influences in diabetes. Intensive work at the cellular level is uncovering abnormalities that involve not only deficiencies in insulin production and secretion, but also in processes essential to normal insulin action. Complementing this research are clinical efforts to develop more effective drug therapies for diabetes and better methods for regulating blood glucose levels. These advances have revolutionized knowledge about and treatment of diabetes. Future studies will exploit the many promising research opportunities for combating this complex disease.

The Diabetes Control and Complications Trial is a major multicenter collaborative clinical trial to determine whether long-term, strict control of blood glucose levels can prevent or ameliorate early vascular and other severe complications of diabetes. This trial is currently in the feasibility stage. By this fall, the Institute, in consultation with scientific advisors, will make a decision regarding whether to enter the full-scale phase of the trial, which would involve long-term study of about 1,200 patients.

The first efforts in islet cell transplantation are now taking place. Should these be successful, the Institute will try to support an expansion of the effort.

Another important diabetes effort is epidemiological and clinical research conducted by NIADDK in Phoenix, Arizona. This year marks the twentieth anniversary of this program's study of diabetes in the Pima Indian population, which has the highest rate of adult diabetes in the world. As a result of this research, we have gained new insights into the relationship of obesity to diabetes, as well as into the risks of diabetes in pregnancy. The Phoenix facility, with the cooperation of the Pima Indian Tribal Council, provides an

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opportunity for research on the development of diabetes in a unique, almost genetically pure population--studies that cannot be done anywhere else in the world. The Institute is taking steps to ensure that data derived from these studies become a national resource for future investigations into diabetes mellitus.

Metabolic abnormalities in various types of Vitamin D resistance have been intensively analyzed and catalogued by our intramural scientists. Our understanding of Vitamin D disorders has increased exponentially in the past few years. New knowledge about the mechanisms by which Vitamin D acts has paved the way to its possible therapeutic use in osteoporosis, hypocalcemia, and many other diseases.

Intensive efforts are under way to uncover the basic metabolic defect in cystic fibrosis (CF), the most lethal genetic disease in Caucasian children. Intramurally, the Institute has brought together a highly talented group of investigators to explore the basic science of CF, one of the most puzzling of the genetic diseases. To date, however, we have been unable to pinpoint the precise genetic defect in this disease and only know its secondary results. Intramural scientists and NIADDK grantees are gaining new knowledge about sweat abnormalities in CF through the isolation of chloride channels. They have found that bovine lung secretes mucin much as does the human lung, and this now permits study of mucin in health and in cystic fibrosis.

Exciting endocrinology research findings are paving the way to an array of potential new therapies, as investigators identify, characterize, and synthesize new peptides. We have made remarkable progress in understanding a variety of growth factors and in identifying hormones essential to growth processes. This knowledge has profound implications for comprehending the roles of small proteins in control of insulin-producing islet cells of the pancreas, in motility of the bowel, and in appetite and satiety. Results obtained from this research are being applied to a broad range of diseases including cancer, rheumatoid arthritis, and other conditions whose causes are not fully understood.

Digestive Diseases and Nutrition: Nutrition research is a critical dimension of studies on many diseases and an essential part of this Institute's intramural and extramural efforts. Intramurally, our scientists are focusing on such topics as calcium, fat metabolism, diet, appetite, satiety, obesity, anorexia nervosa,

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fiber, vitamins and trace metals. Extramurally, nutrition research is important to the programs of all our divisions. We are trying to learn more about the role of nutrition in cystic fibrosis; to determine the appropriate doses of calcium as a preventive approach to osteoporosis; to assess the efficacy of low protein diets in slowing the progression of chronic renal disease; and to resolve the several questions of dietary supplements in patients receiving total parenteral nutrition.

Research is steadily progressing on digestive diseases, which cost an estimated $35 billion in total annual economic loss. Of particular importance is the study of at least six new neuropeptides--small protein hormones--that have been found in the gut. These peptides are known to react with the gut's own nervous system to cause changes in motility, secretion and function. They may also be important signals of appetite and satiety. This is one of the rapidly moving frontiers in gastroenterology and will receive emphasis from the Institute in the years ahead.

Another example of progress is the finding by our intramural scientists that some severe diseases of the digestive tract are caused by substances secreted by tumors. Recently, these scientists have reported that a new, long-lasting analogue of the hormone somatostatin is effective in suppressing deleterious effects of tumor secretions. Preliminary research by other investigators suggests that somatostatin analogues can control symptoms of gastrointestinal tract tumors, can reduce growth hormone levels in patients with acromegaly, and may have wider use in the treatment of malignant tumors. The Institute will seek to exploit these findings.

Kidney, Urologic and Hematologic Diseases: Kidney disease is a serious public health problem, with the Federal costs of treating end stage renal disease alone totalling over $2 billion annually. I am pleased to report that the Institute has just begun a major multicenter clinical trial to assess the effects of diet therapy on the progression of chronic renal disease. This study is in the planning phase, during which the research protocol will be developed.

In related research, we are trying to understand and develop effective treatments for various urologic diseases. The Institute is planning a major conference in 1985 on benign prostatic hyperplasia, a condition marked by excessive growth of the prostate gland and retention of urine. A pressing need

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exists to develop appropriate animal models of this disease, which affects nearly half of the male population by age 65 and nearly 80 percent of men over age 80, at a medical cost exceeding $1 billion annually.

Blood diseases research continues to be active and productive. Of major significance is work on erythropoietin, the hormone that stimulates production of red cells in bone marrow. The gene for human erythropoietin has been cloned and investigators are using the gene to synthesize erythropoietin in tissue culture systems. It is hoped that in the near future ample amounts of erythropoietin will be available for clinical and investigative use. The potential value of synthetic erythropoietin is enormous, both as a diagnostic tool and as a possible therapeutic agent for a variety of anemias including anemia of chronic renal disease.

Special Activities: Research centers and efforts to train new researchers and provide opportunities for research manpower development continue to be extremely important activities of this Institute. In the coming year, we will be supporting 40 centers encompassing research in arthritis, cystic fibrosis, diabetes and endocrinology, obesity, clinical nutrition, and digestive diseases.

With respect to research training, we will continue to support the same number of trainees as last year. We have raised clinical award stipends in order to make research training more attractive to young physicians, and will continue to feature the new Physician Scientist Award as an important training mechanism.

These few highlights of NIADDK activities exemplify the unprecedented accomplishments and opportunities found in each of this Institute's program areas. We believe we stand on the threshold of ever more exciting and promising research findings, which will be brought to bear on improving health and preventing disease.

Mr. Chairman, the 1986 budget request for this Institute is $519,858,000, a decrease of $19,497,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985 this Institute will fund 613 new and competing grants of which 74 will receive 3 years

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of support. In addition, we will fund 40 centers, of which 4 will receive 2 years of support.

I will be happy to answer any questions.

Biography of Dr. Mortimer B. Lipsett

February 20, 1921. New York, New York

Education: University of California, A.B., 1943; University of Southern California, M.S., 1947; University of Southern California, M.D., 1951.

Professional History: 1951-52, Intern, Los Angeles County Hospital. 1952-54, Resident, Sawtelle Hospital, Veterans Administration, Los Angeles, California. 1954-56, USPHS Fellow, Sloan-Kettering Institute, New York. 1956-57, Assistant Member, Sloan-Kettering Institute. 1956-57, Assistant Attending Physician, Memorial Center, New York. 1957-59, Medical Officer, Endocrinology Branch, National Cancer Institute. 1959-60, Assistant Chief, Endocrinology Branch, National Cancer Institute. 1960-1975, Clinical Professor in Medicine, Howard University School of Medicine, Washington, D.C. 1960-61, Visiting Scientist, Karolinska Hospital, Stockholm, Sweden. 1963-65, Head, Endocrinology Service, Endocrinology Branch, National Cancer Institute. 1966-70, Chief, Endocrinology Branch, National Cancer Institute. Associate Scientific Director, Intramural Research, National Institute of Child Health and Human Development. 1970-74, Chief, Reproduction Research Branch, National Institute of Child Health and Human Development. 1974-76, Director, The Cancer Center Incorporated for Northeast Ohio, Cleveland, Ohio. 1974-76, Professor of Medicine, Case Western Reserve University School of Medicine, Cleveland, Ohio. 1978-present, Clinical Professor, Department of Medicine, Uniformed Services University of the Health Sciences, Department of Defense, Bethesda, Maryland. 1976-82, Director, Clinical Center, National Institutes of Health. 1976-82, Associate Director for Clinical Care, National Institutes of Health. 1982-84, Director, National Institute of Child Health and Human Development.

Professional Organizations: American Association for the Advancement of Science, American Association for Cancer Research, American Federation for Clinical Research, American Physicians Fellowship, Incorporated, American Society for Andrology, American Society for Clinical Investigation, Association of American Physicians, The Endocrine Society, Harvey Society, International Society of Endocrinology, Society for Study of Reproduction.

Honors, Awards: Alpha Omega Alpha, 1950. Alfred P. Sloan Award for Cancer Research, 1955. Diplomate, American Board of Internal Medicine, 1959. Fellow, American College of Physicians, 1962. Superior Service Honor Award, Department of Health, Education and Welfare, 1966. Corresponding Member, German Endocrine Society, 1973. Distinguished Leadership Award of The Endocrine Society, 1976. Senior Executive Performance Award, 1980. Department of Health and Human Services Distinguished Service Award, 1981. Member, Japan Endocrine Society, 1982. Senior Executive Service Meritorious Rank Award, 1982. Distinguished Andrologist Award, 1984.

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Senator WEICKER. Let's start off with the disease with the name of your Institute, arthritis. Has anybody put together an estimate of the economic cost of arthritis in this country?

Dr. LIPSETT. According to the Arthritis Foundation, the economic costs of arthritis are at least $14 billion a year. Rheumatoid arthritis affects some 3 to 7 million people. Then we have, of course, a very large problem with osteoporosis, and osteoarthritis, and both of those affect many millions of people. The Arthritis Foundation economic impact estimate is about $2 billion for osteoarthritis and nearly $4 billion annually for osteoporosis. Osteoporosis is a disease that is seen increasingly in women as they grow older and to a lesser extent in men. There is a loss of bone protein and calcium, and the inevitable consequence is fractures, some of which need extensive hospitalization.

Senator WEICKER. How much real progress has been made in the past decade with arthritis?

Dr. LIPSETT. Let me speak to rheumatoid arthritis. We think that there has been a lot of progress just recently. Several things have happened. First, a very small virus has been identified in biopsies of tissue from patients with rheumatoid arthritis. This virus has been shown to produce a similar type of arthritis in experimental lab animals. As a result of this and other data, a large study is being discussed in which biopsies from patients with rheumatoid arthritis will be examined for infectious agents, such as the parvovirus, mycroplasma, and other viruses and infectious agents. This should answer the question about any of the infectious agents that have been postulated as the cause of rheumatoid arthritis.

Additionally, a new model of rheumatoid arthritis has been developed at the Jackson Laboratories in Maine. This model simulates the development of rheumatoid arthritis in humans very well and gives us a chance to study the initial events in this disease. It turns out that the very first event is a change in the synovial membrane, the membrane that lines the joint and which grows and causes bone resorption. Inflammation comes later. So we are rapidly acquiring new knowledge about this disease process.

In the therapeutic area, an old drug, methatrexate which was first used in the treatment of cancer back in the early 1950's, has now been shown to be effective in some 50 percent of the patients who were unresponsive to all other agents for rheumatoid arthritis. The methatrexate is being used in very small doses, similar to that that has been used in psoriasis and thus will be comparatively safe. This major therapeutic finding will be reported shortly.

I think the other points with respect to research in arthritis in general is that we have managed to attract some very good biochemists, molecular biologists, and immunologists to this field. We have found, for example, that the cartilage is not degenerating just with aging. The changes with age are quite different than the changes seen in osteoarthritis, for example. We can now identify what is going wrong in the cartilage.

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We know, that for some reason in osteoarthritis, some of the cartilage will secrete an enzyme which can cause its own destruction, and we have the opportunity to find an antagonist for that.

We recently held a consensus conference on osteoporosis, and I think the recommendations there were clear with respect to calcium intake and estrogen, but there is so much to be learned in this area. We don't know, for example, what is the best estrogen, and whether a nonestrogenic hormone would do as well, and how long people need to take it, when calcium supplementation should be started and the roles of fluoride, vitamin D, and calcitonin.

SEPARATE ARTHRITIS INSTITUTE

Senator WEICKER. Do you think there is any merit to having a separate institute for arthritis?

Dr. LIPSETT. We have just had the Institute of Medicine report, as you know. I would say that as far as arthritis is concerned, it has been very well supported within this Institute. The fact is that over the last decade, arthritis support has increased 177 percent, whereas the other three divisions range between 138 and 157 percent. So there has been no lack of attention to the support of arthritis. We all recognize that it is a major problem.

I am opposed to it for this reason and for a number of other reasons. First, I think that there would be some inefficiencies in having to build a new administrative staff, which is one thing that would need to be done.

As you can see from my previous discussion, the activities that we are talking about in this Institute sweep across all four divisions. Right now, there is a fairly compact distribution of our efforts, and an ability to work between one division and another. Thus for coordination of research, I believe that the home of arthritis should remain where it is.

In essence, arthritis research is flourishing, both in terms of what has happened to its support, and what has happened to its science. So, I will use the old saying, "If it ain't broken, don't fix it."

Senator WEICKER. It seems to me, that question aside, I have enough to handle this year just in terms of personnel salaries, and all the rest of it, without setting up a new institute. With that aside, really the progress insofar as arthritis is concerned, and I might add also as far as diabetes is concerned, has not kept stride with the progress that has been made in other areas. Maybe it is that we have lived with these things for so long that we have come to accept them, and that is what bothers me.

Diabetes, again, I really haven't seen anything to come on the scene new in the sense of arthritis and diabetes, certainly in my years in the U.S. Senate. We have some unfinished business, I guess is the best way to describe it, in arthritis and diabetes.

Dr. LIPSETT. I think that this is a very perceptive comment, particularly with respect to the glamour of working in a field such as arthritis as compared to heart disease or cancer. All types of arthritis are

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chronic, and we have only recently been able to attract comparably good scientists in this field. As a result, we can now begin to identify some of the problems with respect to collagen and other constituents of the joints and what goes wrong in arthritic disease.

To come back to the original question of a new institute, one of the critical points in the Institute of Medicine report was that a new institute should be shown to improve communication, and priority setting. I think, as I pointed out, the communication is superb, and I don't see how it could be improved. We have extensive collaborations. I have touched on the management. Priority setting results from many inputs—the Congress, the administration, and our multiple advisors, and that will continue.

I accept your comment that arthritis research has not moved as fast, but I don't think that this is from a lack of support because, as I have shown you, the support for arthritis over the last decade has exceeded that for the other divisions of the Institute.

Senator WEICKER. What about the question of grants in the area of arthritis and diabetes, how are they faring insofar as grants are concerned?

Dr. LIPSETT. We maintain the grant pay line at approximately the same levels for all four divisions. In 1986, an additional 25 grants will be made available for arthritis.

DIABETES

Senator WEICKER. I would like to see emphasis put on these two areas. I suppose especially tragic—some of the diabetes that comes to pass, as I gather, in the layman's view of it, by virtue of age, heart disease and the rest. Especially tragic, I consider to be juvenile diabetes.

Dr. LIPSETT. In the field of juvenile diabetes we have made very large strides. I have mentioned pancreatic islet cell transplantation that is just getting underway. That has resulted from 10 years of research.

Another area that has expanded rapidly during the last 10 years is identification of the immunologic problems of juvenile diabetes, and the possibility of preserving islet cells by identifying and preventing very early immunologic attack on those islet cells.

Of great importance is our very large diabetes control and complications trial. This is a 10-year trial, which is looking at the question of whether very tight control of blood glucose levels will obviate or slow down the development of complications in later life. It is these complications that shorten the lives of young diabetics, and, of course, are a great source of physical and economic distress as well.

This trial now is in phase II, which is the feasibility phase. Some 250 patients have been admitted. The results are being analyzed now. The committees will be getting together this summer, and this fall, I and members of the Institute and our advisory groups, will have to come to some decision about going into phase III, which includes the recruitment of approximately 1,000 young diabetics, with comparison of tight control and good control. It is a major effort, an expensive effort, but

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the potential payoff will be great if one can show that tight control really does prevent or slow the appearance of complications.

ARTHRITIS PROGRAM LEVELS

Dr. WYNGAARDEN. Mr. Chairman, it is important that we have protected in the 1985 and again in the 1986 budgets AIDS, Alzheimer, and arthritis, and all three of those areas show program growth in 1985 over 1984, and again in 1986 over 1985 despite the trends in the budget. The arthritis program level goes from $88 million in 1984 to $97 million in 1985, and to almost $103 million in 1986.

Senator WEICKER. I will be perfectly honest with you, I have a good deal more faith in the efforts of NIH than having people wearing copper bracelets.

I have further questions, but Senator Proxmire is going to be in the same predicament I am in vis-a-vis the appropriations hearing commencing on the MX shortly after 10 o'clock. So we will have to submit further questions for the record. I know that Senator Proxmire has some questions.

Senator PROXMIRE. I have some questions, Mr. Chairman, but I understand that we have to go to the other meeting at 10 o'clock.

RHEUMATOID ARTHRITIS

Dr. Lipsett, I am going to ask a question that was asked for the record last year, but never directly answered. Once again this year, Dr. Löe's prepared testimony referred to the use of tetracycline to deal with periodontal disease. Dr. Löe said that "tetracycline has been shown to inhibit the production of tissue collagenase, an enzyme that breaks down collagen, the basic building material of connective tissue, ligaments, and bones." He also pointed out that periodontal disease shares certain features with other inflammatory diseases such as rheumatoid arthritis.

On the other hand, your Institute, in reporting on the use of tetracycline in the treatment of arthritis, referred to a 1971 study indicating that tetracycline produced no significant benefits. I believe the study sample was far too small to be statistically significant.

If tetracycline retards the destructive process of collagenase in the supporting tissue of the teeth, why wouldn't it have some efficacious effect in retarding the action of collagenase in the joints of an arthritic patient?

Dr. LIPSETT. Your question is a very good one, and it is one that we are aware of. In fact, ongoing studies suggest that collagenase is produced by diseased synovium and by cartilage cells. Collagenase is the enzyme that will break down collagen, which is one of the primary constituents of cartilage. This finding was taken note of by both NIDR and us.

Dr. WYNGAARDEN. We have a study in four animal models going on concurrently evaluating tetracycline in these experimental systems.

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Senator PROXMIRE. Why not test the use of tetracycline on human models?

Dr. WYNGAARDEN. That will come if the results are encouraging. We can make measurements in animal models that we couldn't possibly make in humans.

Senator PROXMIRE. Is there any problem or any danger in using tetracycline with human models?

Dr. WYNGAARDEN. We would have great problems evaluating it unless we had something quantitative to measure.

Senator PROXMIRE. Let me ask Mr. van der Voort to pursue this question.

Mr. VAN DER VOORT. This is a drug that is being used and has been used for years by a few people to treat arthritis.

Dr. LIPSETT. There are two questions here. Tetracycline was used under the hypothesis that it was an antibiotic which was effective against a particular agent, and this will be evaluated.

The study that I mentioned to Senator Weicker, where we will be looking at infectious agents in the diseased tissue of the joints will also be directed to that.

It is conceivable, as was just pointed out, that perhaps tetracycline was effective on occasions in arthritis when there was excessive production of collagenase.

GALLSTONES

Senator PROXMIRE. Dr. Lipsett, researchers at the Mayo Clinic recently reported on the use of ether to dissolve gallstones. Apparently the ether is released through a catheter through the skin into the patient's gallbladder. Within a few hours the stones are gone. The Mayo Clinic doctors said that the ether has encouraging potential as a safe and highly effective gallstone solvent but cautioned that for now the therapy should be used only in carefully controlled experiments.

Do you believe that that treatment shows real promise?

Dr. LIPSETT. Yes; indeed. In fact I expect there will be a clinical trial on the use of this particular ether to look at its effectiveness and safety.

Senator PROXMIRE. I understand about 500,000 gallstone sufferers undergo surgery every year to have their gallbladders removed. Is it possible for you to give us some idea as to the savings that might be produced by the use of ether to dissolve gallstones as an alternative to the traditional kind of surgery?

Dr. LIPSETT. I do not know the average cost of gallbladder surgery since there are wide variations in hospitals and procedures but I think a gallbladder operation would be several thousand dollars. If this method works, I am sure that the savings will be appreciable.

Senator PROXMIRE. You seem to be saying it could save $500 million or so.

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PROSTATE SURGERY

Dr. Lipsett, I was pleased to note in your prepared statement that you are planning a major conference in 1985 on benign prostatic hyperplasia—commonly known as enlarged prostate.

I understand that the fatality rate following prostate surgery is very high. Four percent of the patients die within 3 months of surgery. Do we know why?

Dr. LIPSETT. I am sorry, Senator, but those figures for benign prostatic hyperplasia surprise me.

Senator PROXMIRE. Staff tell me that those are the figures. If you have other figures, we would like to see them.

Dr. LIPSETT. The best information we have is that prostate surgery carries a risk similar to that of other major surgery. Transurethral resection has a very low mortality rate.

Senator PROXMIRE. All right.

At a hearing that we held last fall, we learned that there is a great variation in the rate of prostate surgery in different hospital markets. In Iowa, for example, the chances of male residents who reach the age of 85 having undergone a prostatectomy range from a low of 15 percent in one part of the State to a high of 50 percent in another part of the State. Will your conference on benign prostatic hyperplasia consider the surgical variation issue?

Dr. LIPSETT. Yes; I am sure.

Senator PROXMIRE. Will the consensus conference develop guidelines as to when it is appropriate to treat benign prostate enlargement medically rather than surgically?

Dr. LIPSETT. This will not be a consensus conference, Senator, but rather a workshop to look at some of these questions you have just asked. We hope it will suggest directions for research, both clinical and basic. We would, of course, like to develop better medical treatment for benign prostatic hyperplasia.

Senator PROXMIRE. Thank you, sir.

EPIDERMOLYSIS BULLOSA

Senator WEICKER. The committee has expressed a continuing interest in two diseases that affect a small segment of our population, osteogenesis imperfecta and epidermolysis bullosa. Would you like to report on the progress made in these areas, and how much is being requested in your fiscal year 1986 budget for each of these diseases?

Dr. LIPSETT. In epidermolysis bullosa, the 1984 level of support was about $1.5 million, in 1985, it is expected to be $2.2 million, and in 1986 it is estimated at $2.1 million.

What has happened in this disease, in fact, is that a basic defect in this disease has been identified. The use of antibodies has shown that little fibers that anchor the layer of dermis and epidermis together are deficient and this defect is responsible for the widespread blister formation in this disease.

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OSTEOGENESIS IMPERFECTA

In osteogenesis imperfecta, I mentioned that we have identified specific collagen defects in brittle bone disease. Identification doesn't mean that we are in a position to treat it or cure it, but it is the first step in increasing our understanding. We are budgeting about $4 million a year for osteogenesis imperfecta. The amount has gone up slightly from 1984 when it was $3.5 million.

Senator WEICKER. Where does this leave us now in the sense of progress. Would you say that we are further along as you speak to me than we were last year, are we about the same, or where are we? I am going to be seeing these people shortly, when NIH gets through testifying, and I want to be able to respond.

Dr. LIPSETT. I think that when you identify the genetic defect, which is responsible for the disease, you have made considerable progress. We hope that this identification will lead to the development of new therapies. We also will be making a program announcement stating again our great interest to support further research in this field.

Part of the problem, as I mentioned earlier, has been attracting some very good scientists into this area. I think that in the last several years, the movement in all areas of research concerning bone, how bone grows, how it maintains itself, and what happens in the joints, has really blossomed, in part because of Institute support, and in part because new tools are becoming available for sophisticated research.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record.

Dr. Lipsett, this is your first year as the Director of the Institute?

Dr. LIPSETT. I am beginning my first year.

I was previously in the Child Health Institute.

Senator WEICKER. I want to say that I obviously agree with you. Thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

PANCREATIC CELL TRANSPLANT FOR DIABETICS

Question: I am aware that insulin-producing cells have been successfully transplanted into diabetic test animals. What is the status of that research, and what is its potential for use in humans?

Answer: Studies on islet transplantation in experimental animals have progressed remarkably over the last two decades. However, until recently there have been several technical roadblocks to human islet transplantation trials. First, there was a shortage of donor tissue for anything other than the most limited work. The National Diabetes Research Interchange, partially supported by a contract from NIADDK, has now successfully established a pilot network for procurement of human pancreases that has greatly increased tissue availability for numerous investigators. Second, the techniques for physicial purification of islets from the whole pancreas, which were developed in rodent and higher mammal systems, were not successful with human tissue. New techniques have now been worked out specifically for human tissue that offer not only the possibility of providing viable donor islets but can be scaled up and automated to provide sufficient quantities of "starting material" for expanded clinical and laboratory use. Third, related studies have both established the potential for segmental pancreas transplants and also raised new questions that need to be addressed in human diabetes because no entirely suitable animal model exists. The consensus of the scientific community appears to be that the time is appropriate to determine if the techniques developed in animal systems are applicable to humans and whether there may be problems unique to humans that need new solutions. The first trials of islet cell transplantation in immunosuppressed diabetics are now taking place.

Question: What are the next steps that need to be taken, and do you have plans to expand research efforts in this area?

Answer: The NIADDK program staff has begun to develop plans for a significant increase in support to the scientific community should preliminary human trials show high promise. There are two interconnected lines of support which we would propose to establish. The first involves centralized acquisition of research resources. This would include contractual support for (1) an expansion of human pancreas retrieval networks to provide initially 5 pancreases per week increasing to 50 or more per week; (2) a centralized, automated, reproducible pancreatic processing operation for the purification of islets; (3) a unified registry for all patient data from clinical trials; and (4) a program to ensure the availability of various specialized reagents in sufficient quantities for tissue processing.

The second component of the plan would consist of a cooperative, multicenter research program involving a number of independent investigators, each with individual interests and expertise in various aspects of the relevant sciences. This cooperative program would not be a clinical trial as usually conceived, that is, where every participant follows a unified, regimented protocol, etc. Several of the participants might adopt a common clinical protocol in order to pool data, but the essence of this program would be to bring together, in a formalized way, the various talents required to approach the specific goal of human islet

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transplantation as a potential therapy for diabetes mellitus. The anticipated collaboration and sharing of experience will certainly accelerate progress toward this overall goal. Undoubtedly, new basic understanding of human diabetes, immunology, and transplant biology would be an additional by-product of this arrangement. Resource requirements for such an initiative are summarized in the table below:

COOPERATIVE HUMAN ISLET TRANSPLANTATION STUDY
ESTIMATED RESOURCE REQUIREMENTS
(DOLLARS IN THOUSANDS)

	Year 1	Year 2	Year 3
Contracts:	$1,750	$2,375	$2,725
1. Pancreas Procurement			
2. Pancreas Processing (Islets)			
3. Transplant Registry			
4. Specialized Reagents			
Cooperative Agreements:			
10-12 participating grantees	3,500	4,000	4,250
Total Funding.....	$5,250	$6,375	$6,975
Staff (FTEs).....	1.5	1.5	1.5

Question: Can you do that on 5,000 grants?

Answer: This research effort is not built into the FY 1986 budget request since it is based on recently emerging scientific opportunities. We will be consulting with our Council members and other scientific advisors during the upcoming months regarding the technical feasibility of initiating a cooperative human islet transplantation study in FY 1987 through the competitive NIH peer review process.

Question: If this procedure becomes perfected, can you estimate what the savings would be in treatment costs and productivity?

Answer: If islet and/or pancreas transplantation can be perfected as a successful and widely available medical therapy, then it may be possible to eliminate or ameliorate insulin-dependent diabetes mellitus (IDDM). It can be conservatively estimated that the direct and indirect costs of IDDM now approach two to three billion dollars per year. These cost estimates do not encompass the human costs of IDDM, which is second only to cancer as a serious chronic disease of childhood. There is also reason to believe that some of the large number of non-insulin dependent diabetics (NIDDM) may also benefit from this therapy and contribute to the potential savings from the estimated 10 billion dollars per year that NIDDM now costs our country.

Question: How much has been invested in this kind of research?

Answer: The NIADDK spent $3.8 million in FY 1984 in direct support to researchers whose study is closely associated with islet and pancreas transplantation.

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NEW INSTITUTES

Question: The recent National Academy of Sciences study concerning NIH suggested criteria for judging the need for new Institutes. One criterion for creating a new Institute was evidence indicating that the disease area in question was not already receiving "adequate or appropriate attention." Do you believe arthritis research would benefit from the creation of an Arthritis Institute?

Answer: Many in the scientific research community believe as I do that removing the Arthritis, Musculoskeletal and Skin Diseases programs from related basic science disciplines, such as endocrinology and metabolism, would hinder, rather than promote, scientific advances. A separate institute for arthritis would fragment the scientific effort, diminish scientific communication, add to the burden of program coordination, and add administrative costs without ensuring increased appropriations. I agree with the Institute of Medicine Report on the Organizational Structure of the National Institutes of Health which says that NIH has reached a point at which there should be a presumption against the addition of institutes except under unusual circumstances.

Question: Is the research priority of the Arthritis program likely to increase if an Arthritis Institute is not created?

Answer: Arthritis research is currently flourishing under the stewardship of the NIADDK. Scientists have recently obtained evidence of a parvovirus in the inflamed joint tissues of those afflicted with rheumatoid arthritis, suggesting that a virus may be the initiating causal factor in this disease. Evidence has also recently surfaced that indicates that substance P is a mediator of inflammation in rheumatoid arthritis, demonstrating a link between the nervous system and the pathogenesis of rheumatoid arthritis. These advances have been achieved at a time of strong and vigorous support for arthritis research in NIADDK's arthritis research program. The Arthritis Division benefits from research in other divisions such as immunology, cell biology, endocrinology, and nutrition. These linkages now are very close.

In recent years, the relative growth of the Arthritis, Musculoskeletal and Skin Diseases Division has been greater than that of any of the other divisions of the Institute. A Secretarial initiative in the FY 1986 President's Budget for arthritis and related musculoskeletal diseases will provide for substantially increased research in this field. As a result, the NIADDK plans to fund 25 additional grants supporting research in rheumatoid arthritis, osteoarthritis, and osteoporosis in FY 1986.

Question: Will arthritis research lose any money because of the cost of running a new Institute?

Answer: If a separate arthritis institute is created and additional appropriations are not provided, arthritis research funds may have to be diverted to cover the administrative costs of establishing and maintaining a separate arthritis institute, and arthritis research would almost certainly suffer.

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Question: What in your estimation will it cost to set up a National Arthritis Institute?

Answer: The net administrative cost of establishing a separate institute for arthritis is estimated to be several million dollars.

Question: How much does your budget include for arthritis research in FY 1986? What is the comparable amount for FY 1985?

Answer: The NIADDK budget estimate for research and training in arthritis and related musculoskeletal diseases is $68.4 million for 1986, which compares with $68.7 million for 1985. For NIH as a whole the budget estimates are $100 million for FY 1986 and $101.5 million for FY 1985.

ARTHRITIS AND ANTIBIOTIC THERAPY

Question: For the past several years this Committee has received testimony from a host of arthritis patients who claim to have been helped by antibiotic therapy. We have received your report on this subject. Please bring us up to date about your plans to conduct a clinical study in this area.

Answer: We are actively oursuing the suggestion by a special Task Force of the National Arthritis Advisory Board as reviewed by the Board itself, and since that time, by other arthritis research advisory groups, of an in-depth search for mycoplasma and other organisms in the joint tissues of patients with rheumatoid arthritis. We are preparing and will be disseminating a Program Announcement for applications in this area for research grants utilizing the cooperative agreement mechanism.

We are pleased to report that Dr. Thomas McPherson Brown, who has had extensive experience with antibiotic therapy of rheumatoid arthritis, and his new colleague, Dr. John Trimmer Hicks, of the National Hospital's Arthritis Institute in Arlington, Virginia, have submitted a research grant application to the National Institutes of Health on March 1, 1985, on "Controlled Antibiotic Treatment of Rheumatoid Arthritis." The proposed project period is from January 1, 1986, to December 31, 1988. First year proposed direct costs are $990,883, and the three-year costs are $2,177,661.

We are also pleased to report that a research grant application on "Evaluation of Tetracyclines in Models of Arthritis" was submitted for the March 1, 1985, deadline. This proposed study is designed to determine whether tetracyclines may inhibit the development of arthritis or suppress arthritis, not by antibiotic or anti-bacterial action, but by other mechanisms such as suppressing the production of destructive enzymes such as collagenase.

BRITTLE BONE AND EPIDERMOLYSIS BULLOSA

Question: The Committee has expressed a continuing interest in two diseases that affect a small segment of our population: osteogenesis imperfecta and epidermolysis bullosa. Have we made any progress in these areas?

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Answer: I am pleased to report progress in both of these areas.

Osteogenesis Imperfecta: Osteogenesis imperfecta (O.I.) is one of the more common types of heritable disorders of connective tissue. It is not one disease, but rather a group of genetic disorders that result from molecular defects of connective tissue leading to a weakened skeleton with varying degrees of liability to bone fractures. Additional associated features that occur in some, but not all, affected individuals include blueness of the sclerae, presenile hearing loss, dentinogenesis imperfecta, hyperextensibility of ligaments, and cardiovascular complications. Currently, classification of O.I. includes four types and two subtypes based on clinical features.

Collagen defects are generally accepted as major factors in causing osteogenesis imperfecta. Structural or regulatory mutations have been shown within the gene coding for the chains of Type I collagen. Recent research has shown that these mutations lead variably to decreased synthesis of structurally normal collagen, to production of a molecule lacking the normal ratio (2:1) of Type I to Type II collagen, or to the synthesis of a molecule containing a defective chain. As a result of these defects, tissues fail to accumulate sufficient normal collagen to provide an adequate scaffold for skeletal strength and for somatic growth. Other studies suggest that there may also be abnormalities of certain non-collagenous proteins, such as osteonectin in osteogenesis imperfecta.

NIADDK supports several projects directly related to O.I. The most exciting advances are in the area of molecular biology where new probes are available to identify segments and individual components of collagen chains. Specific molecular defects in lethal forms of O.I. have been discovered. In one of these, one half of the procollagen alpha-1 chains were shortened. In assembling the triple helix with alpha-1 and alpha-2 types of procollagen chains to make collagen, the defective components became irreversibly bound to the normal chains and amplified the impact of the problem. In a very recent and remarkable study mRNA was isolated from a lethal form of O.I. The defect was found to be a single amino acid substitution, cysteine replacing glycine, 27 units from the carboxyl-terminal. As procollagen molecules are twisted and assembled to form the final structurally useful collagen, the process is initiated from the carboxyl-terminal end. Therefore, a single pin-point defect, such as this, can alter a major portion of the collagen and render it largely ineffective as a supporting structure.

Important research is also being pursued in non-lethal forms of O.I. Again the defect is in a collagen molecule. One of the two alleles capable of producing the procollagen chains has been found to be nonfunctional. Attempts to produce collagen result in an incomplete splicing of collagen into an unusable form. The other allele is functional, and a reduced quantity of normal collagen results. Probes are being developed to detect this condition. The hope for future treatment will be early identification of this genetic deficiency and stimulation of the competent allele to produce more collagen.

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In February 1985, a Program Announcement was issued by the NIH to stimulate further research in O.I. Now that there appear to be several biochemical bases for O.I., grant applications may include applying this new information to larger groups of patients with this disease in its various forms to determine the relative frequencies and importance of each of the molecular defects that have been and will be discovered. These studies can utilize techniques of protein chemistry and/or molecular biology to characterize the primary biochemical abnormalities. It may prove possible to recreate one or more of these molecular abnormalities in cultured cells or animal hosts using gene transfer technology. Further use should be made of a bovine model of O.I. that has recently been discovered.

Research could also focus on specific clinical applications of these emerging new technologies. Novel and rapid methods to pinpoint mutations within the collagen genome and utilization of oligonucleotide probes to identify individuals carrying a specific mutation need to be developed. Families, in which the presence of osteogenesis imperfecta can be identified by a biochemical marker, could be studied to determine the predictability of clinical manifestations, quantitative measures of bone mass, histomorphology of bone, and then specific therapeutic modalities in patients with osteogenesis imperfecta.

Epidermolysis Bullosa: Epidermolysis bullosa is a rare but very serious group of skin diseases affecting approximately one newborn in 50,000 live births. In recent years, it has become apparent that the basic defect in the group of diseases termed epidermolysis bullosa lies within the basement membrane zone of the skin. During this same period of time there have been rapid advances in monoclonal antibody and other immunologic techniques, cell and organ tissue cultures, and in biochemical techniques that have generated an explosion of interest in the normal biology of and specific defects in the basement membrane zone. These new technologies are being applied to research in patients with epidermolysis bullosa and hold promise for a great increase in our understanding of these diseases.

Epidermolysis bullosa research has been a significant part of the Skin Diseases Program of NIADDK for several years. In FY 1984, NIADDK supported 14 research grants, totaling $1.46 million, whose primary emphases were investigations relating to the biology of the basement membrane zone and defects found in epidermolysis bullosa. Among the research highlights in the past year are:

1. Evidence that there is much greater genetic heterogeneity in epidermolysis bullosa than was heretofore recognized. In the past, epidermolysis bullosa was divided into four diseases: the simplex type, the letalis or junctioned type, and the recessive and dominant dystrophic types. It is now recognized that each of these types need to be further subdivided. There appear to be at least 18 different genetic types of epidermolysis bullosa. This is of vital importance in that the basic biologic defect may be different in each genetic type of epidermolysis bullosa even though the final clinical presentation in some types may be similar. Proper identification of the type of EB is necessary so that the results of research are interpreted correctly, and that interventions are developed for specific underlying defects.

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2. In the serious recessive dystrophic form of epidermolysis bullosa, a marked decrease or absence of anchoring fibrils, that hold the two main layers of skin together, has been discovered as a product of research that uses both electron microscopy and monoclonal antibodies.

3. Immunofluorescent and monoclonal antibody techniques have facilitated the development of a more rapid diagnostic test for the characterization of at least the broad categories of epidermolysis bullosa. Previously, electron microscopy was necessary to determine which form of epidermolysis bullosa was present. With the development of new immunologic techniques, it is possible to use light microscopy to make these distinctions more rapidly and thus diagnose and institute appropriate therapy earlier than before.

4. With the use of electron microscopic, immunofluorescent, and tissue culture techniques, prenatal diagnosis of epidermolysis bullosa has become feasible and available as a research tool.

5. Monoclonal antibody techniques have fostered the identification of new proteins and other antigens in the basement membrane zone of normal skin. Some of these may prove important in delineating further the defects of epidermolysis bullosa, as well as in understanding normal structure and function of skin.

Because of this increasing interest, the NIADDK prepared and released a Program Announcement in September 1984, requesting research grant applications to investigate the basic biology of the basement membrane zone and the defects that may exist in epidermolysis bullosa. This Program Announcement generated seven responses in the six weeks immediately after its release. Of these seven applications, many appear to be of sufficient scientific merit to be funded in FY 1985. Some of these proposals were submitted by individuals whose previous research expertise was in an allied area but not directly in epidermolysis bullosa or the basement membrane zone of skin. Therefore, one of the major objectives of the Program Announcement, to attract individuals with appropriate scientific expertise into the area of EB and basement membrane zone research, has been met. Among the areas of research that these new projects address are:

1. New models of epidermolysis bullosa and the biology of the basement membrane zone, both in animals and in tissue culture.

2. Continued use of monoclonal antibody techniques to identify new antigens in the basement membrane zone which may be defective in epidermolysis bullosa, and then to characterize the structure and function of these antigens.

3. Investigations in tissue culture of biochemical abnormalities in the metabolism of collagen and other structures in the basement membrane zone that may underlie the defects in some forms of epidermolysis bullosa.

In addition to the seven applications received immediately after release of the Program Announcement, additional applications

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have been received very recently, following the March 1, 1985, deadline. These applications are still being processed and, if found scientifically meritorious, would be awarded early in FY 1986.

In summary, research in epidermolysis bullosa is accelerating rapidly. New techniques and technologies are being applied to the study of the basement membrane zone in normal and in diseased states, including epidermolysis bullosa. Individuals with no previous research history in epidermolysis bullosa or the basement membrane zone of the skin are being attracted to the pursuit of research in this area. New research being proposed holds the promise of further advances in understanding EB and for the development of new therapies for this extraordinarily distressing condition.

Question: How much is being requested in your FY 1986 budget for each of these diseases?

Answer: While specific allocations are not made for any of our disease areas since grant awards are made on the basis of competitive review of scientific merit, based on a proportional projection from FY 1984 and FY 1985, we estimate funding levels in FY 1986 of about $3.8 million for osteogenesis imperfecta and $2.1 million for epidermolysis bullosa.

Question: Do you have any plans to initiate any clinical trials in the near future?

Answer: Clinical trials in osteogenesis imperfecta await additional scientific evidence suggesting promising therapeutic interventions.

Fibroblasts from patients with recessive dystrophic epidermolysis bullosa elaborate an abnormal enzyme called collagenase. This may be the cause of the decreased or absent anchoring fibrils in this disease. In tissue and cell culture, this abnormal collagenase is sensitive to the effects of dilantin. This sensitivity has resulted in therapeutic trials of dilantin for recessive dystrophic epidermolysis bullosa with preliminary indications that it is an effective treatment for at least some patients with this form of the disease. These studies are now being supported in a larger scale multicenter trial by the Food and Drug Administration.

KIDNEY STONES AND GALLSTONES

Question: We have been reading about recent techniques that can be used to remove kidney and in some instances gallstones without the use of surgery. Please describe these techniques, and tell us if NIH funding played a role in these developments.

Answer: Bladder stones have largely disappeared as a major medical problem in industrialized countries. It is estimated that more than 95 percent of the urinary tract stones in the U.S. occur in the kidney and upper urinary tract.

Principal methods used to remove stones from the kidney and upper urinary tract are open surgery, Extracorporeal Shock-Wave Lithotripsy (ESWL; the so-called "stone smasher"), percutaneous

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lithotripsy, and medical management. Another technique currently undergoing development in urology at the University of Maryland Medical School involves the use of coagulum. Coagulum is a highly gelatinous substance which is now placed through a small incision, and is capable of permeating throughout the kidney. The spongy substance is then removed carrying within it all of the stones. The investigators are currently working on introducing the substance through percutaneous techniques. The method also has been used successfully to remove stones from the biliary tree of the liver. The truly non-surgical treatment technique is ESWL. The NIH has long provided support for the medical management of kidney stones but did not contribute to the development of ESWL or the use of coagulum. However, NIH has a history of strong support for basic and clinical research projects on stones of the kidney and upper urinary tract. Three orphan drugs have been developed for the treatment of stones using NIH funding, and several of these projects are ongoing.

Question: How much could be saved by these new treatments?

Answer: Cost estimates are highly varied and to a great extent dependent on the section of the country sampled. It would appear as if the major cost reductions are from reduced lengths of stay in the hospital following ESWL and percutaneous techniques in contrast to open surgery, and by the patient's ability to return to work relatively soon following the use of techniques not requiring major surgery. The medical treatment of stone disease will be the least expensive of all treatments in that long-term hospitalization is not necessary. Some of the latter techniques are being worked out entirely on an outpatient basis using medicines which are relatively inexpensive.

The financial savings accrued by using the lithotriptor appear to have the potential to be great, although the estimates in this area vary considerably. The costs for a single treatment may vary between $3,000 and $4,000; costs of the hospital stay of several days after receiving the treatment will vary also depending on the prevalent costs in a given area. Some estimates place the total cost savings over surgery between $2,000-$4,000. The initial outlay for the lithotriptor and the necessary service contracts is considerable and, given a limited number of patients in a given area who may require treatment, the cost-effectiveness of the purchase and treatment may not be great. However, the reduced hospital stay, reduced risks by avoiding major surgery, the increased patient comfort, and the ability to return to work much earlier after having stones removed by the lithotriptor all suggest the non-invasive technique to be a method of choice in treating kidney stones.

There are no firm national data on the number of patients who might benefit from lithotriptor treatment. A number of estimates have been put forward. According to the data released when Secretary Margaret Heckler announced approval of the device, between 80,000-100,000 Americans annually undergo surgery to remove painful kidney stones. Others have estimated that from 2-4 percent of Americans form kidney stones at some time in their lives.

NUTRITION/DISEASE PREVENTION

Question: Nutrition has recently been making a great deal of

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news in the area of cancer prevention. What are the connections between nutrition and the diseases that are studied in the NIADDK?

Answer: Nutrition research cuts across many fields of biomedical investigation. NIADDK is deeply involved in studies of primary nutrition, both intramurally and extramurally, as well as in the conduct of clinical trials in categorical health areas. The fact that nutrition research shares many areas of research with metabolism and endocrinology is a source of strength because the latter two are fields in which NIADDK is preeminent.

The Intramural Research Program's scientists in the field of nutrition meet periodically to discuss research findings of common interest, to enhance collaboraion and communication. Nutrition research is also a vital part of the NIADDK extramural programs, not only in the Nutrition Program itself, but as a research area that bears on categorical disease studies in each of the NIADDK extramural divisions.

Some specific examples of nutrition research related to diseases studied in the Institute include:

- o The relationship between obesity and Type II diabetes, including one research center devoted to obesity as well as research grants investigating pharmacokinetics in obesity, the role of neuropeptides in appetite regulation, thermogenesis, measurement of energy expenditure, and metabolism of energy.

- o Studies of calcium absorption in bone, mechanisms of calcification and bone remodeling, action of vitamin D sterols, and the role of hormones in the prevention and treatment of osteoporosis, a major public health problem in this country.

- o The role of diet in end-stage renal disease, including an Institute-supported clinical trial to evaluate the effectiveness and safety of a low protein/low phosphate diet on progression of chronic renal disease.

- o Research in blood and nutrition, including the determination of any significant long-term or short-term effects from minimal deficiency of nutrients such as iron, folate, and vitamin B_{12} and if so at what point in growth and development; how iron absorption is controlled, how iron overload causes damage, and how excess iron can be removed from the body; what effects drugs such as antibiotics have on the synthesis and absorption of vitamin K; and the benefits and hazards of iron fortification of food.

Question: What is your Institute's commitment to research in nutrition?

Answer: Basic research in nutrition has served to lay the foundation of our knowledge about the function and requirements of nutrients, the relationship of diet (and nutrients) to health and disease, and the prevention and treatment of diseases through the application of this fundamental research. As discussed in detail in

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the previous question, nutrition studies are essential to the research areas addressed by Institute intramural and extramural scientists. Other Institute activities in the field include continuing support for Clinical Nutrition Research Units (CNRUs), which provide a mechanism for developing a focal point for high quality, interdisciplinary clinical nutrition research through enhancing and enlarging the scope of nutrition research, building on a base of biological, clinical, and behavioral research. The Institute also serves as the lead Institute in the Nutrition Coordinating Committee, which seeks to enhance coordination and communication in nutrition research among the Institutes supporting research in this field.

In FY 1984 the Institute provided $36 million for research in nutrition and the projections are for more than $40 million to be funded in this area in FY 1986.

STAFFING PROBLEMS

Question: We have had several discussions concerning staffing problems at NIH. Has your Institute experienced any difficulty in attracting or retaining senior scientists?

Answer: While the excellence of our intramural program remains extraordinarily high, it is true that difficulties do arise in recruiting and retaining senior scientists.

Question: If so, to what do you attribute this difficulty?

Answer: I think it is fair to say that these difficulties are often attributable to the inability of NIH to provide salaries competitive with those comparable positions in industry and academia.

Question: Do you have any innovative programs that are used to recruit and maintain high quality staff?

Answer: We have a variety of recruitment mechanisms, such as our Visiting Scientists Program which provides an opportunity for NIH to benefit from the participation of talented scientists from all over the world as well as an opportunity for those participants to experience the NIH research environment. Another example is a collaborative effort with the Cystic Fibrosis Foundation, whereby we have attracted several excellent fellows to do research in this field in our intramural program. I would note, however, that these approaches involve short-term appointments and are not oriented to the senior scientist seeking a tenured position.

Question: Why would a respected senior scientist want to work at NIH when he probably can get a better paid but equally valued position at a major university?

Answer: Senior scientists who are willing to accept an NIH position at a lower salary than they could easily earn elsewhere, are frequently motivated by a strong desire to be part of the unique NIH research environment. They recognize that NIH offers opportunities not present elsewhere for extraordinarily fruitful collaboration and research productivity. The NIH intramural research enterprise is widely recognized as one of significant research opportunity and

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achievement--as attested to by the seminal research publications and advances it produces. The quality of the program has been recognized in Nobel Prizes and many other honors and awards intramural scientists have received over the years.

Question: How much additional money in FY 1986 would be needed to attract and retain qualified staff -- at what level of salary?

Answer: The FY 1986 budget request will enable NIADDK to maintain high quality in its intramural program. The question of providing competitive salaries to senior scientists and other senior officials is one that is not unique to NIH and would therefore perhaps best be addressed at a government-wide level through an agency as the Office of Personnel Management.

FULL-TIME EQUIVALENTS (FTES)

Question: In FY 1984 your intramural research program supported 519 full time equivalents (FTEs). In FY 1986 you are requesting support for only 477 FTEs, a reduction of 42. In contrast, your research program budget will increase by $4 million. It would seem you are doing more research with fewer people. Can you explain how you plan to accomplish this?

Answer: Both our intramural full-time equivalent (FTE) positions and research program budget are decreasing over time. In FY 1984, our FTE total was 519. In FY 1985 and FY 1986, it will be 481 and 477, respectively. The intramural research budget was $53,282,000 in FY 1984. In FY 1985 and FY 1986, it will be $59,807,000 and $57,093,000, respectively. The budgetary increase you note in FY 1985 is largely attributable to pay raises and mandatory cost of living increases.

Question: Can you assure me that intramural research would not suffer as a result of the FTE reductions?

Answer: The intramural program will continue to support high quality research at the budget and FTE levels provided. It is true, however, that the program is heavily dependent on research manpower and that FTE reductions can be expected to have an impact on the scope and rate of research.

LYME DISEASE

Question: Lyme, Connecticut, has the dubious honor of having an arthritis disease named after it. But I understand that progress has been made in the treatment of Lyme Arthritis. How many people have contracted this disease?

Answer: You are correct. Lyme arthritis, now called Lyme disease because it also affects the skin, heart, and nervous system, was discovered as a separate entity in 1975 by Dr. Allen C. Steere, an NIADDK-grantee from Yale, because of close geographic clustering of 12 affected children in Lyme, Connecticut, with what was considered to be juvenile rheumatoid arthritis.

Since that time, hundreds of people have contracted Lyme

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disease along the Atlantic Coast, in some midwestern areas, especially in Wisconsin, and in some western states, particularly in Northern California and Oregon. Cases of Lyme disease are being monitored by the Centers for Disease Control. The epidemiology and ecology of Lyme disease are fascinating subjects. They were discussed in detail at The First International Symposium on Lyme Disease in New Haven on November 16-18, 1983. The Symposium's proceedings were published in the Yale Journal of Biology and Medicine 57:449, 1984 (July-August).

Question: How successful is the treatment and are there any long-term effects?

Answer: Lyme disease has now been discovered to be caused by a spirochetal form of bacteria; specifically a Borrelia. The antibiotics—penicillin, tetracycline, and erythromycin--have all been shown to be effective in treatment. They speed the healing of the skin lesions, and prevent or reduce the severity of the subsequent arthritis. Dr. Steere recommends intravenous antibiotics to treat the neurologic complications of the disease.

CLINICAL TRIALS

Question: Clinical trials have been supported by this Committee in the past; last year we funded 49 across all the Institutes. What are some of the new clinical trials that should be conducted by your Institute?

Answer: Some examples of the clinical trials to which I would give highest priority include: a comparison of estrogen and progestogen vs. estrogen vs. neither in preventing postmenopausal osteoporosis; the use of exogenous human erythropoietin for the alleviation of the anemia of chronic renal diseases; the efficacy of 13-cis retinoic acid in treating keratinizing disorders; and a controlled trial of ligation in the treatment of hemorrhoidal disorders.

Question: How much additional funding would be necessary to get them under way?

Answer: The first year costs would be about $500 thousand for the estrogen/progestogen trial; $750 thousand for the erythropoietin trial; $400 thousand for the retinoic acid trial; and $400 thousand for the hemorrhoid treatment trial.

KIDNEY CENTERS

Question: Over the years we have heard requests for a variety of research centers in your institute. Are there any Centers specifically for kidney diseases, and if not, can you explain the reasoning behind that?

Answer: There are no kidney centers in NIADDK. We support a variety of research programs at both the clinical and fundamental levels. Our total funding for kidney and urology research and training was $53.7 million in FY 1984. There has been a proposal put forth from the research community that a centers program be developed in each of the six following areas:

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- o Hypertension
- o Diabetes mellitus
- o Obstructive and heritable diseases of the urological system
- o Nutrition and toxins
- o Immunology
- o Cellular injury

We appreciate the research community's interest in establishing specialized centers of research, but cannot provide support for these endeavors under our current funding levels. We would anticipate that these centers would have a first year annual budget of $600,000 per year for each center, escalating to a cost of $1,000,000 per year per center by the end of five years. The units described above would be too circumscribed and some would overlap with programs of other Institutes and other Divisions within this Institute. Centers in kidney disease research would provide a valuable focus around which basic and clinical scientists could gather.

SPECIALIZED CENTERS OF RESEARCH (SCORS)

Question: Support appears to be growing for the establishment of Specialized Centers of Research (SCORs) for various forms of arthritis. Can you comment on the value of SCORs as research entities, and can you describe the difference between SCORs and Multipurpose Arthritis Centers?

Answer: Specialized Centers of Research (SCORs) provide a highly effective means of concentrating research personnel, resources, and facilities on selected high priority research areas in diseases of national importance. The research efforts of the individual centers are multidisciplinary, including both a basic science and a clinical research emphasis, to ensure that advances in the basic sciences are rapidly translated into clinical applications and that clinical imperatives will provide a direction for the basic science.

A multidisciplinary research team is emphasized as an important characteristic of applications for SCOR support. The objective of the SCOR concept is to encourage active collaborations among scientists and disciplines, not merely informal interactions.

The Multipurpose Arthritis Centers provide support for coordinating existing activities and for developing new capabilities in rheumatic diseases research, and education and community/health services research activities, the three components of a Center. The goals are: (1) to develop and foster new methods for the prompt and effective application of available knowledge; and (2) to develop new knowledge. The approaches are multidisciplinary and flexible, and may involve any area of rheumatic disease. Center funds support multiple and diverse development and feasibility studies in research and technology transfer areas, and core units in research and evaluation methodology. Biomedical research projects are supported through other mechanisms, including NIH research grants.

The following table illustrates some of the differences between Specialized Centers of Research and Multipurpose Arthritis

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Centers:

SPECIALIZED CENTERS OF RESEARCH (SCOR) P-50	MULTIPURPOSE ARTHRITIS CENTERS (MAC) P-60 (Comprehensive Centers)
Research Area in Specified Major Health Problem (e.g., Osteo-arthritis)	Diverse Research Areas in Any Rheumatic or Musculoskeletal Disease
Designated by Institute	Selected by Applicant
Series of Biomedical Research Projects	Biomedical Research Projects Supported by Other Grants (NIH and Others)
Basic and Clinical Research	(Basic and/or Clinical Res.)
No Developmental and Feasibility Studies	Developmental and Feasibility Studies (pilot, small) in: Biomedical Research Educational Research Community/Health Services Research
	Innovative Education and/or Community/Health Services Research Projects
*Core Units--Research	*Core Units--Research Biostatistical Research Design and Evaluation

*Common facilities and/or resources serving several projects

Question: What areas of arthritis research would be targeted under a new SCOR program?

Answer: The Institute has received numerous suggestions for research areas in many different important rheumatic and musculoskeletal diseases to be addresed by a SCORs program. Of these, three seem eminently suitable for research emphasis: rheumatoid arthritis, osteoarthritis, and osteoporosis--each a major national public health problem--with a minimal critical mass of three Centers (SCORs) for each disease.

PERCENTAGE OF GRANTS FUNDED

Question: Can you review for us year-by-year the fluctuations that have occurred between grants approved and grants funded in your Institute?

Answer: Since 1979, those figures are as follows:

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	Number Approved	Number Funded	Percent Funded
1979	1,494	769	50.0
1980	1,628	698	42.8
1981	1,840	759	41.0
1982	1,985	645	32.5
1983	1,993	777	38.9
1984	2,020	785	38.8
1985 (Est.)	2,071	613	29.9
1986 (Est.)	2,321	631	27.2

Question: What percentage of approved grants should be funded in order to maintain scientific momentum and scientist morale?

Answer: We believe that it would be appropriate to support 40-50 percent of the approved applications.

RESEARCH PRIORITIES

Question: There has been continued discussion concerning the relative commitment on NIH as a whole toward the following: basic research, disease prevention research, and disease-specific applied research. What percentage of the NIADDK research budget is used for each of these areas?

Answer: About 71 percent of our budget is for basic research and about 25 percent is for disease prevention; however, these are not mutually exclusive areas and there is an overlap between them. There is no standard definition for disease-specific research and we generally try to relate most of our basic and clinical research projects to the various diseases under our purview, perhaps 90 to 95 percent. The remaining 5 to 10 percent is related to very fundamental studies in areas such as molecular and cell biology which underpin the whole of our research efforts but are not readily identifiable with a specific disease or medical problem.

RESEARCH PRIORITIES

Question: Your Institute has research responsibility in several disease areas and must be responsive to a varied constituency. What criteria are used to establish your short and long-term priorities?

Answer: NIADDK annually produces an Implementation Plan that identifies major advances from the past year and initiatives for the coming year for each program of each Division. The initiatives include plans for workshops, conferences, and research solicitations. Research initiatives are included for several reasons such as: a major advance in scientific understanding or technology has opened numerous opportunities for further advancement; an area is identified as one of particular interest to the Congress, the Administration, or the public; program staff and scientific advisors have identifed a new, emerging field of research that needs to be brought to the attention of investigators in order to encourage work in this area; a health problem is identified and research efforts need to be focused on it.

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Question: Who is involved in setting these priorities?

Answer: These priorities are developed throughout the year in discussions between program staff and scientists and at meetings with National Advisory Boards, members of the Advisory Council, and ad hoc scientific advisory groups. The Institute makes the final determination of research priorities to be included in the Implementation Plan.

Question: What procedures do you use to respond to the need for emergency research?

Answer: The Institute has not had much experience in dealing with emergency research as the diseases which are within its mission are of a chronic nature. Having the capability for a quick and effective response to a public health emergency is, however, important to the Institute. The tremendous value of the pool of talented researchers that constitute our intramural program is very clear. Congress recognized the importance of this type of readiness in passing the PHS Public Health Emergency Act, P.L. 98-49, enacted on July 13, 1983, which provided that the Secretary "may take such action as may be appropriate to respond to public health emergencies."

DIGESTIVE DISEASES

Question: I note that digestive diseases affect over 50 percent of the U.S. population at a cost of over $50 billion annually. Why does the digestive disease program receive about 12 percent of your budget?

Answer: The amount of our budget which we spend on any of our many disease areas is primarily determined by the scientific merit of the proposed studies as evaluated by independent peer review groups. We try to maintain a truly competitive system and support the best science in each area, as reflected by priority scores and percentile ranking.

CENTERS

Question: According to your budget justifications, you do not plan to expand the number of research Centers from your FY 1984 level. The FY 1985 appropriation provided funding for four additional research Centers. What research Centers will not receive funding?

Answer: By the time we were directed to fund only 40 centers in 1985 we had already made commitments for 36 awards and only have four possible awards left. We will not make the final decisions on which four to select until all the competing applications have been peer reviewed and we have received the recommendations of our National Advisory Council which will meet in May.

Question: How many highly rated Center applications have been approved for funding?

Answer: We have received 24 applications which are competing for these four remaining slots but we do not yet have all the results of the ratings by the peer review groups.

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Question: How does this funding shortfall affect your Institute's long-range goals?

Answer: The Institute will continue to give highest priority to the most meritorious investigator-initiated research grants as they are judged by the peer review system at NIH. While the value of Centers is clear and we will make every effort to provide for stable funding for Centers, a funding shortfall means that there would be no expansion of the Centers program.

AVERAGE COST OF RESEARCH GRANTS

Question: I note that the average cost of a research project grant will increase by 11 percent, from $140,000 to $158,000. With the inflation rate hovering at only 4 percent, why are you projecting an 11 percent increase in costs?

Answer: In 1985, we are having to cut direct costs below recommended study section levels. The OMB allowed a 4.6 percent inflation factor and the remainder of the increase is largely attributable to instrumentation and other costs associated with increasingly sophisticated research techniques, and to the cyclical nature of the grants process.

Question: How did you arrive at that figure?

Answer: The projected full costs of our grants for both FY 1985 and FY 1986 are estimated by a computer model developed by the Division of Research Grants which makes projections based on the last five years of historical data.

Question: How accurate have your projections been in the past?

Answer: A recent analysis of the NIH grants projection model showed that the accuracy of the average grant size projected two years in advance varied by less than plus or minus two percent.

Question: Is this price increase justified in your view?

Answer: Yes. It is very much in line with the Research and Development Price Deflators developed by the Congressional Budget Office and considerably below the estimates developed by the independent Delegation for Biomedical Research.

PREVENTION RESEARCH

Question: In a speech before the American Pharmaceutical Association, Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: Many diseases under study at NIADDK have yielded to basic research, and scientists are now designing means of prevention that will be translated into health care practice if they are shown to be safe, effective, and feasible. Major examples of ongoing prevention research activities are:

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Prevention of post-menopausal osteoporosis and its sequellae, that is, fractures of the vertebrae, hip, and wrist. This is the most common bone disease, affecting approximately 16 million people over the age of 50 years. In osteoporosis there is an accentuation of loss of bone with age, predisposing older individuals to fractures of the hip, spine, and wrists even under minor mechanical stress. These fractures cause an extensive amount of disability, particularly among older women. Fractures of the hip in this population result in high eventual mortality, ranging from 15 to 30 percent during the first post-fracture year. The human and economic impact of osteoporosis in the U.S. is immense. Studies in progress have developed evidence that low-dose estrogen administration and maintenance of adequate calcium intake, 1 gram per day, from age 40 years on will significantly and appropriately suppress bone resorption.

Prevention of the emergence and progression of Type II (formerly "maturity-onset") diabetes in individuals with an inherited tendency for this disorder. Generally speaking, persons at risk are obese individuals with a strong family history of Type II diabetes. In the United States there are about 5 million known patients with Type II diabetes; epidemiologic data indicate the existence of another 5 million individuals with the as-yet urecognized disease. Emerging research evidence suggests that weight reduction, attainment of lean to optimal body weight, adherence to sound diets, and regular physical exercise will reduce the metabolic abnormalities and clinical symptoms in most patients with this type of diabetes. The NIADDK diabetes program supports a broad range of research to define the relationship between body weight, exercise, and diabetes, and to determine whether life-long maintenance of normal body weight and physical fitness can prevent the development of non-insulin dependent diabetes.

Prevention of the appearance and progression of the clinical complications of Type I (formerly "juvenile-onset") diabetes. This grave disease requires daily administration of insulin for maintenance of the life of the patient. Even though this treatment has extended the average life span and improved the quality of life of patients with Type I diabetes, it has not prevented the development of the chronic progressive degenerative changes in various tissues which lead to heart attacks, strokes, kidney failure, gangrene, blindness, and damage to the nervous system. Most of the morbidity, mortality, and economic cost associated with diabetes is due to these degenerative tissue changes. There is a long-standing, unresolved controversy over whether strict and precise control of blood glucose levels in persons with diabetes will prevent these life-threatening degenerative changes. Recently developed technologies permit, for the first time, studies to assess whether "tight" metabolic control will prevent the diabetic complications. As a result of these advances, the NIADDK has now initiated a collaborative clinical trial on the relationship between blood glucose control and the vascular complications of diabetes mellitus. A pilot study involving approximately 280 patients has been started as a forerunner for a long-term, well-controlled clinical trial.

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Prevention of obesity. Obesity plays a significant role in the development of cardiovascular disease, especially hypertension, the emergence of latent Type II diabetes, osteoarthritis of the weight-bearing joints, gallbladder disease and gallstones, certain types of cancer, and the detrimental somatic and psychological aspects of morbid obesity. A major research effort related to obesity and its prevention is supported by NIADDK.

Prevention of the recurrence of kidney stones. Urinary tract stone disease (urolithiasis) is one of the most common renal-urologic diseases and represents a significant world health problem. In the United States, at lease 1 percent of the population will develop urinary tract stones, primarily in the kidneys. Moreover, in many patients, even if stones are passed or surgically removed, new stones tend to develop. Recent NIADDK supported research has shown that painful kidney stone formation and its recurrence, if due to excessive absorption of dietary calcium, can be inhibited and prevented by sodium cellulose phosphate, which binds calcium in the intestine and prevents its absorption. Other studies have shown that the sequence of events leading to the formation and recurrence of magnesium ammonium phosphate, "struvite", stones can be prevented through the blocking action of acetohydroxamic acid. Based on these studies, the Food and Drug Administration has recently approved both drugs, which fall into the "orphan drug" category. Similarly, recent studies have demonstrated that recurrence of another type of kidney stone can be prevented effectively, virtually eliminating the need for surgical intervention, with use of potassium citrate, taken orally in a coated, slow-release form.

Lyme Disease. A recently discovered new form of arthritis known as Lyme disease, after Lyme, Connecticut, where it was first acknowledged, has been shown to be caused by a bacterial spirochete carried by ticks. Prompt diagnosis and treatment with antibiotics can control this type of arthritis and prevent joint damage.

Identification of Carriers. A method for identifying carriers of the gene for Maple Syrup Urine disease has been developed. Previously, there was no way to identify suspected carriers of this inherited metabolic disease, and thus, genetic counseling to avoid pregnancies that could result in infants with this devastating disease (which is the case when both mother and father are asymptomatic carriers) was not possible.

Prenatal Diagnosis. New and sensitive assays for the prenatal diagnosis of sickle cell anemia and Cooley's anemia have been devised. These assays improve on previous techniques which required in utero sampling of fetal blood, a risky procedure. The new assays have extreme sensitivity, allowing the use of uncultured amniotic fluid cells withdrawn from the mother by relatively simple and safe procedures.

Other Prevention Research. The above are just a few examples of ongoing prevention-related research. Other such research activities include research related to prevention of the recurrence of peptic ulcers in patients with known history of the disorder; research on the factors that predispose older men to the development of benign prostatic hyperplasia, with the aim of eventual prevention or amelioration of this widespread disorder; and many others.

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Question: What percent of your budget is directed to preventive research?

Answer: Based on standard NIH definitions and reporting procedures, approximately 25 percent of our budget relates to disease prevention research.

Question: How are the results of this research being translated into useful public information?

Answer: Important and relevant research findings are being presented in scientific/medical meetings and constantly being published in the scientific and medical literature to make them available as soon as possible to research workers (for further verification if this is necessary) and to health professionals for application in patient care. In addition, a number of NIADDK programs bring the latest findings in disease prevention to the attention of the medical and public health community, to health providers, and to consumers and the public-at-large. A few examples follow:

Multipurpose Arthritis and Diabetes Centers. These centers have education and demonstration components with information, continuing education, and training programs for medical and allied health professionals and for patients. Of particular importance to prevention are programs of education and dissemination of information for the general public concerning the risk factors associated with disease; the importance of early diagnosis and treatment; and discouragement of the use of unapproved and ineffective treatment measures.

Clearinghouses and Office of Health Research Reports. The Institute supports national information clearinghouses on arthritis, diabetes, and digestive diseases, which serve the information needs of a broad professional and health education constituency in a number of areas relating to disease prevention and health promotion. The clearinghouses act as central resources for information concerning the availability of scientific and popular literature and produce specialized newsletters, fact sheets, bibliographies, and other publications. The Institute's Office of Health Research Reports is a central resource for information on NIADDK's research programs and categorical disease areas. This function is accomplished through the production and dissemination of information brochures for the lay public concerning various diseases and through an active information service to science writers and the major public communications media.

Clinical Nutrition Research Units. Supported by NIADDK at selected medical schools, CNRU's are designed to strengthen multidisciplinary research in clinical nutrition; to improve education and training of medical students, house staff, hospital-associated practicing physicians, and paramedical personnel in clinical nutrition; and to enhance improved patient care through better institutional support services. These innovative programs encourage the principles of disease prevention and health promotion by striving to upgrade the use of nutrition knowledge in clinical practice.

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Special Activities. This includes regularly scheduled events like the Institute's annual Diabetes Day--a postgraduate seminar for practicing physicians organized and presented by the Institute's intramural staff.

Consensus Development Conferences. This special type of conference which is widely announced and advertised to practicing physicians, professional and voluntary agencies, consumer organizations, and the public-at-large, as being organized whenever new research findings make it imperative or desirable to bring them to the attention of health professionals and consumers. This special type of conference has very heavy press and media coverage, and the issues involved are widely disseminated to practicing physicians and --by the media--to the public at large. Two recent examples very important to disease prevention were:

1. A consensus conference on the treatment and prevention of osteoporosis, organized by NIADDK, which has resulted in significant professional and lay interest--particularly in the prevention of this widespread disease.

2. A recent Consensus Development Conference of Health Implications of Obesity, organized by NIADDK and the National Heart, Lung, and Blood Institute, which focused on the prevention of a number of widespread diseases for which obesity is a definite risk factor, and on obesity-related shortened life span. Here again, the findings presented had a widespread impact throughout the U.S. because of strong interest both by the medical community and the public-at-large and the very effective coverage of this conference by the public media.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: This Institute will continue its efforts to increase efficiency and reduce administrative costs through a variety of means such as the use of integrated word-processing equipment and the networking of personal computers. We recently consolidated logistical support contracts and internal administrative staff for three national advisory boards and three information clearinghouses. We already have one of the highest workload-to-staffing ratios of any of the institutes regardless of the index, that is, number of applications processed, number of awards made, or number of dollars awarded.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: We have a continuing program to maximize the use of and to upgrade automated word and data processing and we constantly review staffing and vacancies to ensure that the impact of staffing reductions on our research programs is minimized.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

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Answer: We have not made any changes other than those prescribed by law or regulation. As noted previously, we are making efforts to increase the productivity of our decreasing workforce and have benefited from efficiencies at the NIH level, such as improvements in processing grant applications and awards by the Division of Research Grants.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: NIADDK gives high priority to always maintaining and, where possible, increasing the standards of fairness and efficiency that have characterized the peer review of research applications. Along these lines, this Institute recently initiated a system of percentile ranking, in addition to priority scores, to adjust for discrepancies in study section voting behavior.

NIADDK supports a two-stage peer review process and all research proposals go through this same process. Proposals are first reviewed by study sections for scientific and technical excellence. If the necessary expertise for review is not present on a study section, ad hoc reviewers may be asked to participate, and/or outside opinions may be requested. Every effort is made to avoid a conflict of interest on the part of the reviewers. Study sections assign a priority score which is then converted to a percentile ranking to adjust for any possible difference in study section voting patterns. An applicant may appeal a study section recommendation by submitting an amended application or requesting re-review by another Initial Review Group.

The National Advisory Council provides the second review of grant applications. Although Council decisions concur with study section recommendations in the majority of cases, Council members also consider the goals of the Institute, research initiatives, and program relevance when voting for approval of applications.

All during the grant application process, program staff perform a vital role in advising new applicants of the process; attending study section meetings, as observers, in anticipation of a possible need to elucidate the study section recommendations to Council members; and maintaining thorough familiarity with the proposed research, site visit reports, and all correspondence.

The two-stage peer review process, the applicant's right to appeal, and the strong involvement of reviewers, Council members, and program staff ensure equitable and thorough review of all applications.

RESEARCH PRIORITIES

Question: Please comment on the recent study by the Office of Technology Assessment entitled, "The Hemodialysis and Disposables Industry," regarding the following issue. The OTA reported that an 83 percent decline in NIADDK support for research concerning end-stage renal disease (ESRD) maintenance therapies, including

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hemodialysis and peritoneal dialysis, occurred from 1979 to 1983. This decline and a shift in research priorities at NIH toward alternative therapies, such as kidney transplantation, was justified because of the noted movement of industry into dialysis research. Will this decision reduce the value and credibility of dialysis research because of potential conflicts of interest within industries which fund the research?

Answer: In 1966, the Congress mandated the creation of an Artificial Kidney-Chronic Uremia Program at the NIH which was located in our Institute.

The Artificial Kidney-Chronic Uremia Program was in existence as a targeted contract research and development program for approximately 13 years. During this time it had been instrumental in the development, directly or indirectly, of most of the innovations that constitute today's maintenance dialysis treatment and other approaches to the treatment of end-stage renal disease (ESRD). By that time, the Federal Government had undertaken to fund the ESRD treatment of about 95 percent of the patients suitable for treatment and requiring it. A sizeable industry had been developed to supply the devices used in this treatment program. Dialysis had advanced to the point where rehabilitation was possible for the majority of patients and the annual mortality rate was relatively low.

At this point it was felt that the industry had reached a critical size and level of sophistication where it could, and would, undertake its own research efforts to further dialysis technology and devices, while NIADDK would utilize a progressively greater proportion of the funds supporting the work of the Artificial Kidney-Chronic Uremia Program for much-needed research into the causes and pathophysiology of the kidney diseases which were responsible for end-stage renal failure. It was thought that only through improved knowledge in this area, would it be possible to prevent these diseases, to treat them more effectively, or to slow their progression to kidney failure, so that fewer patients would eventually require ESRD treatment.

The NIADDK's kidney research programs periodically issue announcements about the research needs in the renal area in general or the field of ESRD in particular, to the relevant research community. These announcements, which influence the nature of research proposals submitted to the Institute, are often based on recommendations sought from ad hoc advisory committees to the Kidney and Urology Diseases programs and frequent consultations of program staff with outside scientists knowledgeable in the various relevant disciplines which are pertinent to ESRD.

With the passage of P.L. 97-219, an amendment of the Small Business Innovation Development Act (SBIR) of 1982, intended to stimulate technological innovation, to meet Federal research and development needs, to increase private sector commercialization of innovations derived from Federal research and development needs, and other purposes, the NIADDK Chronic Renal Diseases program has focused its SBIR efforts on solicitations limited mostly to the area of maintenance dialysis therapies. The topics included in these solicitations are:

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- o Studies of biocompatibility of artificial kidney membranes, in surface sensitive proteins, complement, and clotting mechanisms
- o Development of minaturized models for hemodialysis
- o Development of continuously functioning artificial kidney
- o Safer means of catheter connections to reduce the incidence of peritonitis episodes encountered in Continuous Ambulatory Peritoneal Dialysis (CAPD) patients, including the use of filtration, antiseptics, X-rays, ultraviolet light, heat, etc.
- o Improvement of CAPD dialysis-bag connection sites
- o Improved techniques of preservation and storage of kidneys intended for transplantation

As new research needs are identified, either new SBIR solicitations or general research Program Announcements (PA), Requests for Applications (RFA), or Requests for Contract Proposals (RFP) will indeed be issued.

In fact it is within the Institute's plans to convene once again an ad hoc advisory committee to review the state-of-the-art and to identify areas of research needs in the overall ESRD field.

It is the Institute's belief that industry's undertaking its own research efforts to further dialysis technology and devices should not reduce the value and credibility of research, but perhaps the contrary may result.

RECOMBINANT DNA/HUMAN GENE THERAPY

Question: Issues concerning recombinant DNA and human gene therapy research have received a great deal of attention in recent years. What potential applications does such research have for diseases within the NIADDK program areas? Does NIADDK currently fund research programs in recombinant DNA or gene therapy research?

Answer: Advances in isolating genes, determining their structure, creating biological probes for genes, and gene cloning have provided new investigative and clinical tools for research. Many of the applications for these tools are just beginning to be realized.

A new process is being used to identify different collagen types and how they are defective in different forms of osteogenesis imperfecta. This involves developing oligonucleotide probes that are used to "pull out" and isolate genes so their structure can be determined. The normal gene is then characterized so that mutant genes can be identified. Technology such as this is being applied to several genetic diseases.

Isolation of genes for enzymes and hormones is now permitting synthesis of large quantities to be produced for administration to correct enzymatic or hormonal imbalances. Already, genetically synthesized human insulin and growth hormone have been produced and are in clinical use. The gene for coagulation Factor VIII has been isolated and Factor VIII synthesized. This will eventually provide therapy for hemophilia without the risk of contamination with hepatitis virus or the agent responsible for AIDs. The gene for

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human erythropoietin has also been cloned and expressed. Quantities of this erythropoietin should be evaluated in the management of the anemia of renal failure.

There are over 150 inborn errors of metabolism for which specific enzymatic defects inside cells have been identified and characterized. The most promising candidates for gene therapy are enzyme deficiency diseases in which bone marrow transplantation has been effective, indicating that the enzyme produced by bone marrow cells is able to have an effect. These diseases include mucopolysaccharidosis and citrullinemia. Isolation of the genes coding for the missing enzymes in these disorders holds great promise for their therapy, but many technical problems remain to be solved.

NIADDK supports research programs to characterize genetic structures and develop gene therapy research. This spring, NIADDK will sponsor a workshop on genetic methods for the diagnosis and treatment of familial disorders. The workshop will assess the state-of-the-art of genetic technology and stimulate the development of genetic techniques.

Questions Submitted by Senator Mark Andrews

LIVER TRANSPLANTATION

Question: In the budget justification for FY 86, it states that NIADDK will establish a research data base for liver transplantation. When will this be implemented?

Answer: We have been moving forward on this project and expect to award a contract to establish the data base, perhaps as early as May of this year.

NUTRITION

Question: NIADDK focuses a great deal of attention on nutrition. This has proven a very effective health preventive health measure. Are these efforts coordinated with the Department of Agriculture and does your Institute engage in joint research efforts with the Department of Agriculture?

Answer: The National Institutes of Health and the Agriculture Research Service of the Department of Agriculture provide each other with research updates. The objectives of the research within the Department of Agriculture are different from the objectives of nutrition research within the National Institutes of Health. NIH is disease oriented, while the Department of Agriculture places emphasis on research in the area of food technology and nutrition and its physiological role in the normal subject. Thus, we do not have joint research efforts per se; however, as research on these objectives can intersect, some grantees hold research grants from both the Department of Agriculture and the NIH.

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Question Submitted by Senator William Proxmire

RESEARCH MANAGEMENT AND SUPPORT

Question: On page 219 of your justifications you indicate you will be spending $14,855,000 for research management and support in 1985. This is almost $2 million less than your original budget request and about $1,750,000 less than the amount shown as your adjusted 1985 appropriation in the "effect of Congressional action" report. Can you explain this discrepancy?

Answer: This reduction was a directive given during the budget formulation process. It requires absorption of all normal cost increase plus formula reductions in specific areas such as use of expert professional consultants, travel, and printing.

We have yet to develop operational plans to accomplish the required reductions.

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NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

STATEMENT OF DR. MURRAY GOLDSTEIN, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN DIRECTOR, NATIONAL INSTITUTES OF HEALTH

WILLIAM MATTHEWS, BUDGET OFFICER, NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator WEICKER. Next we welcome Dr. Murray Goldstein, the Director of the National Institute of Neurological and Communicative Disorders and Stroke.

The budget request for this institute is $373.8 million, which is $23 million less than last year's appropriation.

Dr. Goldstein, please begin.

RESEARCH OPPORTUNITIES

Dr. Goldstein. Thank you, Mr. Chairman.

In the recent decade, neuroscience has transformed our knowledge of the human brain from one steeped in philosophy and metaphysics to one based on molecular biology, neurochemistry, and cellular neurology. The research opportunities that exist today to understand the health and diseases of the nervous system and human communication are truly at the forward edge of medical science, opportunities characterized by tremendous advance and excitment.

For the record, I am submitting with my opening statement, a list of research opportunities and areas of excitement that the 1985 appropriation has permitted us to address. They range from understanding the molecular workings of 10 billion individual nerve cells that make up the human brain to the implantation of new cells in destroyed areas of the brain, with the goal of restoration of function.

Even if we cannot yet repair injured brain cells, the concept that dead brain cells can be relaced with new ones offers hope for patients with stroke, Alzheimer's disease, and cerebral palsy.

As an aside, this methodology of cell implantation in the brain has been demonstrated to be feasible.

In the area of clinical trials, two important trials are underway. One demonstrates that the technique of blood cleansing, called plasma-

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pheresis, has an important role in the treatment of postinfectious paralysis, known medically as Guillain-Barre' syndrome. This postinfectious paralysis affects 3,000 persons a year. The results of this trial, which cost $900,000, will save $35 million annually in hospital costs by shortening hospital stays and respiratory therapy, and, of great importance, it will return full function to many patients threatened with paralysis and death.

The second trial has involved 50 institutions all over the world, and it has tested the efficacy of a surgical bypass procedure to revascularize the brain threatened by an impending stroke, the so-called extracranial-intracranial bypass. Five years of follow up of 1,400 patients was completed on March 20 of this year, and in July we will be able to advise physicians whether this much heralded surgical procedure is useful and if the results justify the procedure.

PREPARED STATEMENT

In summary, Mr. Chairman, the basic and clinical research programs of the National Institute of Neurological and Communicative Disorders and Stroke are at the beginning of fulfilling a promise that neuroscience research offers. I hope that my written statement adequately documents that promise.

I will be happy to respond to any questions that the subcommittee has about these most exciting and productive areas of research.

[The statement follows:]

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Statement of Dr. Murray Goldstein

The explosion of knowledge in the neurosciences that we have discussed in years past is clearly accelerating. We are well on our way to learning how the brain and nervous system function in health as well as in specific illnesses. Scientists supported by this Institute, including the Senator Jacob Javits Neuroscience Award recipients, are hard at work on a full range of basic and applied research topics. Their work is critically important because disorders of the nervous system are not only life-threatening but also seriously impinge upon the quality of life.

Some neurological disorders, like stroke, Huntington's, Tay-Sachs, and Alzheimer's disease, kill, often after long periods of disintegrating health. Other disorders, attacking in the prime of life, do not kill but cause permanent, progressive disabilities. Some of these, like multiple sclerosis and myasthenia gravis, have a unique course in each patient. Neither physician nor patient can predict the next remission or exacerbation, the next part of the body to be affected. Some of the 600 disorders under NINCDS purview are inherited diseases. Among these are neurofibromatosis, Gaucher's disease, familial Alzheimer's disease, and Huntington's disease. Patients with these diseases must face the devastating disorder itself as well as the horrible possibility of passing the disease to their children. Some diseases have no external physical stigmata but, like epilepsy, severe hearing loss, and autism, affect the mind and functional abilities. Neurological disorders, such as stroke or head and spinal cord injuries, may strike suddenly and are among the major cripplers and killers of our society. Parkinson's disease, amyotrophic lateral sclerosis and others manifest slowly, debilitating over a long period.

Few, if any, neurological disorders are yet preventable or curable. With drugs or medical devices, we can control the symptoms of some of these diseases, such as epilepsy and hearing loss. But for the great majority of patients with neurological and communicative disorders, current medical knowledge can only ease symptoms.

We are making progress. There are many examples. This year in a multi-institution study of the paralyzing Guillain-Barre' disease, we learned that plasmapheresis, a treatment in which part of the patient's blood is replaced with an artificial fluid, greatly speeds recovery. The patients who received plasmapheresis spent less time on respirators, had far shorter hospital stays, and left the hospital in better condition. Research on hearing loss has also been successful. The Food and Drug Administration recently approved a single channel cochlear implant to aid the profoundly deaf. Scientists in the NINCDS Intramural Research Program identified a new inherited neurological disorder, a leukodystrophy which was previously diagnosed as multiple sclerosis. They have determined the pattern of inheritance of the disease and how to diagnose it correctly.

SELECTIVE VULNERABILITY

The concept of "selective vulnerability" refers to a disease process that attacks a specific portion of the brain or central nervous system, initially harming only that segment but eventually

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reverberating throughout the body. Five specific disorders, Parkinson's disease, amyotrophic lateral sclerosis (ALS), Alzheimer's disease, Huntington's disease and hearing loss, illustrate different types of vulnerability.

Parkinson's Disease. Parkinson's disease is a severe crippling disorder that attacks approximately one percent of Americans over the age of 60. Uncontrollable tremors of the arms or legs, muscle rigidity, and immobility are its major symptoms. Depression strikes many patients. The disease is usually progressive; the average patient is severely disabled within five to ten years of onset. The cause of the disease is unknown.

The part of the brain first affected by Parkinson's disease is the substantia nigra, which is responsible for producing much of the brain's dopamine, a neurotransmitter or chemical that enables coordinated movement. Parkinson's disease results from a shortage of dopamine, starting in the substantia nigra, but causing havoc throughout the body. To treat the disease, NINCDS-supported scientists developed levodopa, the metabolic precursor to dopamine that, unlike actual dopamine, can cross the blood-brain barrier and treat the symptoms of the disease. Related drugs called dopamine agonists are also effective. These drugs have a drawback; they eventually lose their effectiveness for many patients or cause severe side effects.

In the past year, a major discovery has revitalized research in Parkinson's disease and changed our conception of the disorder. Serendipitously, scientists discovered that drug addicts using an improperly made heroin developed extreme symptoms of Parkinson's disease. The heroin contained a chemical, abbreviated as MPTP, which kills the brain cells in the substantia nigra. Using this information, scientists have developed new drug and animal models of Parkinson's disease. We now are learning why symptoms of the disease appear in some animals but not in others. We know which metabolite of MPTP might cause the disease and how it is converted from the innocuous form of MPTP to the nerve-cell killing MPP by another chemical found in the brain, monoamine oxidase (MAO). Perhaps most importantly, we have learned how to prevent this type of permanent Parkinsonism in animals, by treating them with a drug that inhibits the MAO from affecting the MPTP. This research, supported by NINCDS, is bringing a new understanding of the disease and its potential causes. It can lead to prevention of Parkinson's disease in susceptible people and to safer, more effective treatments for victims.

ALS. Amyotrophic lateral sclerosis (ALS) is another devastating neurological disease. While it spares the intellect, ALS is a progressive disease and ultimately paralyzes and kills its victims. Its cause is not yet known and there is no way to arrest its progress.

The specific "selective vulnerability" in ALS is the motor neuron, the nerve cell that innervates voluntary muscles and connects the spinal cord and brain to the muscles. In ALS patients, the motor neurons begin to die. When the nerve cell withers, the muscle under its control weakens and wastes away, and patients lose the ability to walk or write, speak or swallow. The degeneration of the motor neuron is the key event in ALS and we are

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trying to determine why that occurs. A lack of the trophic factors that feed and nourish the nerve cell in healthy people or the cell's inability to use them may cause ALS. Scientists recently discovered that some ALS patients have an antibody that destroys a trophic factor necessary for sprouting of peripheral nerves after injury. In some cases, the remaining neurotrophic factors may not be transported from the cell body to the axon of the cell where they are needed and the cell may die. Scientists funded by the NINCDS are exploring these hypotheses, as well as another abnormality of ALS neurons, the accumulation of clumping of small neurofilaments that swell the nerve cell and perhaps eventually destroy it.

Huntington's Disease. The "selective vulnerability" in Huntington's disease is the genetically caused damage to a section called the caudate nucleus, deep in the brain. While we can now locate the initial damage, we do not know why it occurs. The first signs of this fatal, incurable disease usually occur in most patients in their mid-thirties. While they carry the Huntington's gene from conception and will irrevocably have the disease, it is not manifested until the brain cells die.

We are learning a great deal about this devastating disorder. With the recently discovered genetic marker, we are getting closer to finding the aberrant gene but we do not yet know how this gene programs the cell's destruction. Scientists funded by NINCDS are using positron emission tomography and other new brain imaging technologies to disclose early, presymptomatic signs of what the gene does to cause cell death.

Alzheimer's Disease. Alzheimer's disease is a "living death" to the more than one million elderly Americans who suffer from it. Alzheimer's disease robs victims of their memory and minds. Five percent of Americans over the age of 65 are demented and the number rises sharply with increasing age. There is no treatment for this eventually fatal disease.

The "selective vulnerability" in Alzheimer's disease appears in a part of the brain associated with memory. The cells in the nucleus basalis die and their death seems to cause a shortage of a brain chemical ChAT, an enzyme responsible for synthesizing a key neurotransmitter. Other focal areas of brain vulnerability are now being identified and the clues to understanding the neurological basis of this disease are coming into focus.

Research in Alzheimer's disease has been productive and multifaceted. Scientists funded by the NINCDS studied the anatomy of the Alzheimer's brain and discovered selective damage to nerve cells in two parts of the hippocampus. This damage may explain the memory loss that is often the first sign of the disease.

The NINCDS is supporting scientists at the NIH and elsewhere who are investigating genetic and other agents that may be the basis for the disease. This year there is new evidence that a genetic influence requires further study. One group of scientists funded by the NINCDS recently discovered that the cores of the plaques in the brains of Alzheimer's victims are very similar and perhaps identical to a long-acting, virus-like infectious agent that causes a degenerative disease in sheep. This finding suggests that some

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Alzheimer's disease may be triggered by a latent virus. The controversy surrounding this research and the studies of genetic factors is encouraging; it reflects the exciting level of research activity in this disease.

Hearing Loss and the Aged. Hearing acuity begins to deteriorate at birth and grows progressively more severe as we age. Deafness or severe hearing loss adds to the isolation that affects many of the elderly. An elderly man with hearing loss might say, "I can hear; I just don't understand what I hear." We know now that this perception and the hearing loss itself results not just from changes in the inner ear but from changes in the brain. The "selective vulnerability" here is likely to be in the neurons in the central auditory cortex.

Our current knowledge of the central auditory system limits our ability to understand these impairments. Why does the nerve cell loss occur? To what extent is it genetically influenced? Why is the hearing loss so much greater than the general aging-related deterioration of the other senses? Is the nerve cell loss related to a deficit in neuro-transmitters or other key brain chemicals? Scientists supported by the NINCDS are currently investigating these questions. Investigators have been examining the inner ear and attempting to correlate hearing function with pathologic findings. They are now also considering changes in the neurons related to hearing in the brain. We hope that these efforts, the first examples of focused coordinated research of this type, will help clarify the hearing process and explain why and how hearing acuity deteriorates.

BRAIN IMAGING

In the past few years positron emission tomography (PET), nuclear magnetic resonance imaging (NMR), and related research technologies have dramatically increased our potential for understanding the human brain. They enable us to study thought, movement, and emotion in ways we could not have anticipated five years ago. With these technologies, scientists can pinpoint potentially salvageable brain tissue after a stroke, identify the exact lesion in epilepsy, and follow the progress of chemotherapy in treating brain tumors. The goal of the NINCDS research program in brain imaging is to use these exciting new methodologies to improve our understanding of central nervous system function and dysfunction.

Mr. Chairman, the 1986 budget request for this Institute is $373,894,000, a decrease of $21,303,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985 this Institute will fund 601 new and competing grants of which 82 will receive three years of support. In addition, we will fund 35 centers, of which one will receive two years of support.

I will be happy to answer any questions.

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NINCDS RESEARCH AREAS OF EXCITEMENT

The biology of the neuron.
The biology and pathology of the receptor.
Metabolic imaging of the brain.
Selective vulnerability.
Neural repair: Axon regeneration.
Infectious particles.
Immunological factors: autoimmune dysfunction.
Replacement therapy: CNS implanation; neural prosthesis.

SENATOR JACOB JAVITS AWARDS

Senator WEICKER. Thank you very much.

Congress established two separate programs at your Institute in honor of Senator Jacob Javits. Can you bring the committee up to date on the Javits awards and the Javits Centers of Excellence?

Dr. GOLDSTEIN. Yes, sir; the first program was initiated 2 years ago, known as the Senator Jacob Javits neuroscience investigator award, these are grant awards to investigators of demonstrated abilities for 7 years of research. One hundred such awards have been made to date. We anticipate that by the time the cycles of review are completed, there will be approximately 200 such awards, which is about 8 to 9 percent of the investigators being supported by our Institute.

Senator WEICKER. These are for 7 years of research?

Dr. GOLDSTEIN. Seven years of research to selected investigators, with distinguished track records.

The second program is a new one being initiated this year as the Senator Jacob Javits Centers of Excellence in Neuroscience. We have advertised and solicited applications. To date, we have received 55 such applications, all of which are presently in the scientific merit review process. Twleve of these centers have been identified as outstanding candidates for the Center of Excellence award.

We are now in the review process. We have not quite completed it, but these applications will be presented to the NINCDS National Advisory Council in the near future.

Senator WEICKER. How will the OMB directive affect these programs?

Dr. GOLDSTEIN. The Senator Jacob Javits individual awards, are not affected because these are the top scientists who are competing for research project support.

In regard for the Senator Jacob Javits centers award, I must report that until yesterday I didn't know what the answer would be. In light of the opinion of the Comptroller General, we should be able to make five such awards.

ALZHEIMER'S DISEASE

Senator WEICKER. I am a little bit confused here. Last year, I was told by the Secretary that we had made a break through on Alzheimer's disease.

Dr. GOLDSTEIN. You have to understand that I am presenting from the neurological research viewpoint, and not from the viewpoint of the social consequences of Alzheimer's disease.

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The more obvious research has been completed during the last 2 to 3 years. There were a number of hypotheses that had to be dealt with. We now have learned that the disease does not start as a gross deterioration of the brain as a primary event, but rather this is the last stage of the disease. It begins in small areas of the brain that begin to malfunction, and it is because that localized area of the brain is malfunctioning that the remainder of the brain is affected.

A good analogy that I think most of us are comfortable with is Parkinson's disease. In this disorder, a small area of the brain, an area which we have identified, degenerates and causes the gross effect that we think of when we visualize the several disorders of a Parkinson patient's.

We now recognize that Alzheimer's disease is probably following the same pathophysiological pattern.

The second research issue is, what are the neurochemical changes? A year ago, I was able to report with a great deal of confidence that we had identified the loss of acetylcholine, a neurochemical in the brain, as the probable basic cause of the disease. Now that we have additional information, that was an oversimplification.

There are a number of neurochemicals that are in very short supply in the brain of the Alzheimer patient. Now the issue is, what is the cause and what is the effect.

What I am trying to say, Senator, is that we now have identified the important questions, but we don't yet have the answers. What looked like a relatively easier issue is now becoming a much more diffuse problem. So will we have an answer to Alzheimer's disease this year or next year, I doubt that. It is a difficult research problem. Permit me to repeat: We now have the neurobiological questions and we have the methods available to look at those questions. It will be a difficult but achievable scientific endeavor to sort out the answers.

Senator WEICKER. These new scanners, are they helpful in the pursuit of knowledge in this area?

Dr. GOLDSTEIN. Yes; positron emission tomography has been and continues to be one of the most important tools for identifying where in the brain the biochemical changes occur, where are the little areas in the brain that start to go wrong. On the x ray scanners, whether they are CT or regular x ray, we see an anatomical picture and can't identify the biochemistry. Also with a new scanner, known as nuclear magnetic resonance [NMR], the biochemical aspect of the pathology as well as the anatomy can be visualized at the same time.

To put it another way, what we are now able to do with the new brain scanners is not only to have anatomical maps of the brain, but also chemical maps. We can see where the chemistry is changing. We are now admitting to our own clinical center in Bethesda and to the other research centers that have biochemical scanners the earliest types of cases to try to identify where the pathology starts and what are the chemical changes that occur. For example, we are studying the glucose metabolism and oxygen metabolism of the brain of patients with Alzheimer's disease.

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Have I answered the question, Senator?

Senator WEICKER. Sure, you have answered the question.

Where do we sit in terms of funding for 1986 as compared to 1985?

Dr. GOLDSTEIN. In the case of NINCDS, in 1985, our Alzheimer's program will be a little over $14 million. At the level of the President's budget for 1986, it will be $13 million.

Dr. WYNGAARDEN. The total NIH effort is $42 million in 1985 and $43 million in 1986 for Alzheimer's disease. The largest effort in Alzheimer's disease is in the Aging Institute.

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Dr. Goldstein, it is an honor to hear you. You certainly have done marvelous work.

On page 5 of your statement, you say that "Alzheimer's disease is a living death to the more than 1 million elderly Americans who suffer from it. Alzheimer's disease robs victims of their memory and minds. Five percent of Americans over the age of 65 are demented and the number rises sharply with increasing age. There is no treatment for this eventually fatal disease."

If I understand the figures, 5 percent of those over 65 would be more than 1 million people. If the number is rising sharply, it seems that 2 to 3 million people are going to be demented in the relatively near future.

Dr. GOLDSTEIN. We need to be careful because there are other causes of dementia.

Senator PROXMIRE. Yes, indeed; that is what I was getting at.

Dr. GOLDSTEIN. In Parkinson's disease, as an example, we now realize dementia often occurs late in the disease. In the past, people with Parkinson's disease did not live long enough to develop the dementia associated with Parkinson's disease. As we are successful in preventing death due to brain disorders, we must now face the issue that as brain cells are destroyed, the person's performance degenerates.

Senator PROXMIRE. Can you tell me what percentage of people who live beyond the age of 85 are suffering from Alzheimer's disease?

Dr. GOLDSTEIN. About 20 percent are demented.

HUNTINGTON'S DISEASE

Senator PROXMIRE. You said in your prepared testimony that we are learning a great deal about Huntington's disease. However, the chairman of the Neurology Department at Johns Hopkins, Dr. Guy McKhann, has been quoted as saying that as a result of research cutbacks the Huntington's disease research centers at Hopkins and Harvard will have to close down by July 1. Why was that decision made?

Dr. GOLDSTEIN. Through the grant program, we support two national Huntington's disease research centers, one in Boston and one in Baltimore. They have been supported for 5 years and have been remarkably successful. They are both excellent science programs. They are presently before us for competitive review.

We must remember that they are competing for grant support with all of our other research efforts. At the level of the 1985 appropriation,

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we had sufficient funds to award one center, and to provide interim support to the second one. This would provide the second center with the time necessary to answer some of the scientific questions that have been raised during the scientific merit review process. That was our original plan.

With the revised budget for 1985, we found our funds insufficient to be able to carry out that plan. We have enough money at this time to provide interim funding to one center, and no funds to provide for the other.

With the statement of the chairman yesterday about the opinion of the Comptroller General, we would be able to go back to our original plan of funding one center and providing interim support to the other.

Senator PROXMIRE. You said that these centers were remarkably successful. Why didn't they get a higher priority?

Dr. GOLDSTEIN. There is severe competition for funding in neuroscience at this time. This area of research is moving so rapidly that it is extraordinarily competitive. The other thing I must say is that when dealing with priority scores, our Institute will be able to fund priorities through approximately 150 in fiscal year 1985. When we are dealing with 5 points or 10 points, the scientific differences are very small. However, we have to have some standard choosing among applications.

You see, sir, I really can't answer your question in a satisfactory way. It is a scientific evaluation, and we have to provide for other opportunities in science at scores better than the second center.

PARKINSON'S DISEASE

Senator PROXMIRE. On page 4 of your prepared statement, you refer to the use of MAO inhibitors to treat Parkinson's disease in animals. A recent article in a publication titled The Sciences had this to say about the subject, "The United States would do well to follow Europe's lead and, at the least, begin to experiment with MAO inhibitors—either deprenyl or paragyline, or both—in combating Parkinson's disease."

Are the Europeans ahead of us in the experimental use of MAO?

Dr. GOLDSTEIN. No, sir; our own clinical center at NIH is on the cutting edge of this development. In our own internal research program, where most of the work has been done on the recently developed experimental cause of Parkinson's disease, our investigators are among the world's leaders.

Senator PROXMIRE. If, as you say in your prepared statement, a chemical contained in heroin can produce the symptoms of Parkinson's disease, is it possible that the traditional form of Parkinson's disease could be triggered or influenced by environmental contaminants that accelerate the natural rate of cell death that accompanies the aging process?

Dr. GOLDSTEIN. Yes, sir; and that is exactly what we are pursuing.

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Senator PROXMIRE. In your prepared testimony, you mention the use of plasmapheresis to treat Guillan-Barre' disease. Does plasmapheresis hold any promise for treating myasthenia gravis or multiple sclerosis?

Dr. GOLDSTEIN. Let me take the latter question first. Senator, in the several small trials of plasmapheresis for multiple sclerosis, it has not yet been proven to be effective It is still very experimental.

Senator PROXMIRE. It has not proven effective.

Dr. GOLDSTEIN. There are anecdotes, though. What we do learn is that a doctor may have treated five cases of multiple sclerosis. As you know, it is a disease that is characterized by exacerbations and spontaneous remissions. Most patients get better temporarily after any treatment or after no treatment at all.

Senator PROXMIRE. My sister suffered from multiple sclerosis for 25 years before she died, and it is a heart-breaking disease.

Dr. GOLDSTEIN. It is a terrible disease.

In myasthenia gravis, plasmapheresis has been used successfully in those cases where the disease is very far advanced or life-threatening. But given the other methodologies that we presently have available, it is really the last resort to be used when the patient is in serious danger of dying. There are easier therapies that are now available. These are usually successful, and there is no reason to go to the most extreme method until it is absolutely needed.

Senator PROXMIRE. Although plasmapheresis is being used at Froedtert Memorial Lutheran Hospital in Milwaukee, because the treatment is so new insurance companies are just starting to cover its cost, yet doctors at the hospital believe the use of plasmapheresis has saved millions of dollars in treatment expenses.

What can be done to make sure that this procedure is eligible for insurance coverage?

Dr. GOLDSTEIN. I would guess that the Federal focal point would be the Health Care Financing Administration, which is essentially the organization which the other third party payers turn to for leadership. In other words, under certain conditions the Government is funding plasmapheresis, and private insurance agencies probably do the same. This information is available from Dr. Carolyn Davis at HCFA. What their procedures are and why they have not pursued it, I am sorry, sir, I just don't know.

Mr. VAN DER VOORT. I was just curious as to whether you had a mechanism to put some emphasis behind the importance of plasmapheresis the people making the decisions in this area could have the benefit of your input, or whether you are just throwing a stone in the pond.

Dr. GOLDSTEIN. What we do do is advise the Health Care Financing Administration about the results of clinical trials, and the results of experimental therapies. Having advised it, our responsibilities are essentially fulfilled. I really don't know how, in the Health Care Financing Administration, subsequent entitlement decisions are made.

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Senator PROXMIRE. Thank you.

MULTIPLE SCLEROSIS

Senator WEICKER. In multiple sclerosis, what is the level of funding in the 1986 budget as compared to last year?

Dr. GOLDSTEIN. In multiple sclerosis, let me give you a figure and explain it. The figure I will provide is for multiple sclerosis and related research, as differentiated from a project which only addresses the disease itself. In 1985, we expect to spend approximately $41 million on multiple sclerosis and related research. At the level of the President's budget in 1986, we will spend close to $38 million, approximately $2.5 million less.

Senator WEICKER. The indicators are that there are fewer suffering from multiple sclerosis?

Dr. GOLDSTEIN. No, sir; I could not draw that conclusion.

Senator WEICKER. You know, I just find the juxtaposition of yesterday's testimony here and the action on the Senate floor, and where we are going in a few minutes, these matters that are presented to us in their various forms, it is just incredible. I don't know what is wrong with this country, I really don't.

We hear a report on Alzheimer's, and there is a $1 million increase, or whatever it is, and the number of those afflicted, and then multiple sclerosis and it carries on all through here, and we are sitting here arguing over these amounts, then when I see what is being thrown into defense, really it is an issue that the American people will have to face. There is only so much that can be done. Maybe sooner or later we will all come to our senses.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

I have further questions for response to the record. I would like to stay longer. Thank you very much, Dr. Goldstein.

Dr. GOLDSTEIN. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

JAVITS' NEUROSCIENCE AWARDS

Question: Congress has established two separate programs at the NINCDS in honor of Senator Jacob Javits. Can you bring the Committee up to date on Javits' awards and the Javits' Centers of Excellence?

Answer: The Senator Jacob Javits Investigator program was initiated by NINCDS in FY 1984. To date, 100 distinguished scientists at the leading edge of science within their particular research areas have been designated as Senator Jacob Javits Investigators. Upon recommendation by our National Advisory Council, awards are committed for a seven-year period; the length of the award provides additional freedom to pursue complex scientific problems. This program has been enthusiastically received by the research community, and other organizations within NIH are considering similar award programs.

The Senator Jacob Javits Centers for Excellence in the Neurosciences is being initiated on a pilot basis in FY 1985. The program will allow collaboration among groups of distinguished scientists whose various backgrounds will provide the basis for new research perspectives. Fifty-five grant applications were received in mid-January and are in the process of initial review for technical merit. We expect to make awards for this program by September, 1985.

Question: How will the OMB Directive affect these programs?

Answer: The Senator Javits Investigator Program is underway and is likely to continue at about current levels. Since the majority of awardees have been judged to be at the highest level of achievement by their peers, the impact of the OMB directive limiting the number of competing awards in FY 1985 is expected to be less pronounced than among other grant supported research activities.

Although it remains our intent to launch the Senator Javits Centers of Excellence Program during FY 1985, the number of centers which can be established may be less than the five originally planned.

Question: What are your plans for FY 1986 for the Javits Programs?

Answer: From among those research grant applications to be funded in FY 1986, we hope to be able to consider additional scientists for designation as Senator Jacob Javits Investigators. We estimate that as many as 50 awards may be made in FY 1986. The 1986 budget will continue the Senator Javits Centers established in 1985, but no new centers will be awarded.

Question: How much funding will be necessary to maintain these centers at current services level?

Answer: The funding level of each Center is expected to be approximately $750,000 in direct costs annually for each of five years. Since the number of awards to be made in FY 1985 is yet to

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be determined, the cost of the program at current services level in FY 1986 cannot be ascertained. Should five centers be established, the current services level in FY 1986 would be approximately $5,000,000.

COCHLEAR IMPLANTS

Question: I have seen a number of stories about the use of implants for the hearing impaired. Has NIH supported this research?

Answer: During the past 13 years the NINCDS has provided extensive grant and contract support to university-based investigators conducting studies directly related to the cochlear implant. These studies have provided a substantial understanding of the principles and problems of inner ear electrical stimulation for the profoundly deaf, and have led to the design of multiple channel inner ear electrodes and electronic sound processors. Many of the key features of electrode and processor design evolved in the course of this Institute-supported work have been utilized by both domestic and foreign companies who have developed or are developing marketable cochlear implant systems.

Question: Has there been any private sector support for this research?

Answer: The first cochlear implant used in this country, a relatively simple single channel device, was developed by the private sector; other companies have supported the development of multiple-channel systems. In general, as Institute-supported investigators have developed improvements in intracochlear electrodes and other associated electronic hardware, the private sector has adopted these improvements and developed them further.

Question: How well do the implants work and what are the future possibilities?

Answer: Even the simplest implants, using one electrical stimulation channel, provide profoundly deaf users with hearing cues that lead to improved voice quality, improved lip-reading skills and awareness of simple sounds, but they do not allow the users to hear conversational speech. There are clear indications, however, that multi-channel implants enable some profoundly deaf users to follow conversation. The Institute continues to support studies that will further improve single and multi-channel devices. We shall continue support of studies to identify deaf subjects who can successfully use a multi-channel device and differentiate those for whom a simple single-channel system will be most useful.

ALZHEIMER'S DISEASE

Question: Alzheimer's disease affects over one million Americans and is a major cost factor in long-term care. What recent progress has been made in the understanding and treatment of Alzheimer's disease?

Answer: Recent research by NINCDS grantees has disclosed that particular nerve cells in the basal nucleus of the brain which are

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associated with memory are selectively vulnerable to destruction in Alzheimer's disease. However it is caused, death of these cells leads to a deficiency of the key neurotransmitter, acetylcholine. Scientists have also identified selective degeneration of specific nerve cells in other areas of the brain in Alzheimer's disease victims; this degeneration causes deficiencies of other vital neurotransmitters. Thus, in Alzheimer's disease, multiple systems appear to be involved in producing the clinical pictures of memory loss and cognitive decline.

Other investigations supported by NINCDS have revealed the presence of material in the cores of Alzheimer plaques which resembles the suspected causal agent of scrapie, a neurodegenerative disease in sheep. This finding suggests that, at least in some cases, Alzheimer's disease, like scrapie, may be triggered by a slow virus.

Families in which there are many cases of Alzheimer's disease are being studied intensively in order to define the possible genetic influences which may predispose individuals to this disease. NINCDS scientists are using positron emission tomography (PET) to identify the areas of the brain afflicted at different stages of the disease. Such investigations aid in understanding the clinical manifestations and sharpen the focus for molecular and metabolic investigation.

These and other recent observations are providing clues to an understanding of Alzheimer's disease which may eventually lead to treatment and prevention. At present, however, no new effective treatments have been discovered.

Question: What are the implications for the future?

Answer: The recent findings in Alzheimer's disease are exciting and point the direction for new investigations. Scientists are now trying to uncover an infectious cause of this disorder, explore any genetic aspects, and further define the metabolic abnormalities which occur in the disease. We hope the results of these studies may lead to specific prevention or treatment methods.

Question: In your opinion, are we applying enough resources to the research efforts in this disease?

Answer: Although we do have pending unfunded applications of very good scientific merit, we believe that progress in this area can be made at the proposed level of $13.1 million for 1986 research support on Alzheimer's disease.

Question: Budget considerations aside, how much should be spent on Alzheimer's research?

Answer: Although it is difficult to offer a precise amount which should be spent on Alzheimer's disease, there are a substantial number of excellent quality grant applications with priority scores which are close to, but outside of, the priority score pay cutoff. Research on Alzheimer's disease would benefit from these awards.

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Question: Staff has informed me of some recent research on a disease in sheep called Scrapie that may have some implications for Alzheimer's research. What is the connection between Scrapie and Alzheimer's?

Answer: Scrapie is a naturally occurring infectious disease of sheep which affects the central nervous system. The disease is characterized by a long incubation period and is classified as a slow virus disease similar to the human dementing disorders, Creutzfeldt-Jacob diseases and Kuru. Several different strains of the infectious agent have been isolated and found to cause a similar disease when inoculated into hamsters and other laboratory animals. In Alzheimer's disease, microscopic structures called neuritic plaques are seen that are similar and perhaps identical to the plaques found in the brains of animals with scrapie. This finding has led to the hypothesis that the type of unconventional agent which causes scrapie may also be involved in Alzheimer's disease.

Question: I understand that Scrapie may be caused by something called a "Prion." What is a "Prion"?

Answer: "Prion" is the term coined by an NINCDS grantee for the putative causal agent(s) of scrapie. Because no nucleic acid (responsible for replication in all known life forms) has been identified in prions as yet, it may represent a unique class of infectious agents. The "prion" does replicate and causes disease in experimental animals. Intensive efforts are underway to confirm and further characterize the unique nature of the "prion" and to establish its possible role in causing brain disease.

Question: How much support is available for this research, and is it enough?

Answer: The NINCDS presently supports three extramural research projects in this area and an intramural research project. The extramural projects are in New York, Wisconsin, and San Francisco. Over $1 million was spent in 1984 on this effort. Since there are a number of high quality unfunded applications for work on slow viruses this year, additional productive research in this area could be funded.

MULTIPLE SCLEROSIS

Question: Multiple Sclerosis is a tragic disease which strikes down thousands in the prime of life. What kind of progress has occurred in this area of research?

Answer: Progress has been made in multiple sclerosis (MS) and related research in recent years. Our understanding of how blood-borne immune cells cause loss of myelin in the brain is much improved. Scientists have identified how viral infections can induce immunologically mediated demyelination. The knowledge of the biology of oligodendroglia, the cells that produce and maintain myelin, and myelin formation itself has increased, as has our understanding of the persistence of a virus in the human host which may trigger disease years later but may cause no symptoms initially.

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There have been significant advances in immunotherapy, with the development of drugs and agents, such as cyclosporin and monoclonal antibodies which will allow highly selective manipulation of the immune system in efforts to treat MS and related diseases. The use of nuclear magnetic resonance neuroimaging permits the early identification and study of the development and resolution of MS brain lesions. It will be a useful tool for objective monitoring of the effects of treatment in clinical trials and may permit a shortening of the time and cost of some future therapeutic studies.

Five double-blind randomized clinical trials of MS therapies are underway. Results of two of these will be available in FY 1985.

Question: What are your funding plans for MS research in FY 1986?

Answer: The NINCDS plans to fund highly meritorious investigator-initiated fundamental and clinical studies which will uncover and clarify the role of the immune system in MS, examine the genetic predisposition and possible causes of MS, and continue a limited program of clinical trials.

SPINAL CORD INJURY

Question: I understand that recent findings have shown that the human nervous system has shown a potential for regeneration. What are the promising avenues of research concerning spinal cord injury and paralysis?

Answer: The NINCDS continues to give high priority to studies of regeneration of the injured nervous system which restores function. It is evident that the nervous system of higher animals attempts a process of regeneration but fails. Use of implants of specific neuronal cells has been an important contribution. The NINCDS supports multidisciplinary programs in three major areas of spinal cord injury. These programs focus on the acute response of the spinal cord to trauma, improved methods of medical and surgical intervention to prevent or arrest further damage, and applied research to develop neuroprotheses to bypass the injured spinal cord or activate paralyzed muscles.

Recent research on nerve cell implants using animal models of experimental brain injury is encouraging in terms of our future ability to repair damage in neurological and communicative disorders. Scientists are currently attempting to determine the signals that activate the machinery for regeneration in nerve cells which do regenerate routinely such as those in the peripheral nervous system. When they understand these signals, investigators can study nerve cells that do not normally regenerate to see if they can be induced to re-extend their axons and regenerate. Investigators are also identifying substances that are present in axons only when they grow or regenerate; such substances should be important for axonal repair and growth. Substances secreted from target tissues may be necessary to insure effective connections and functional recovery. While investigators are seeking these substances they are also examining the utilization of artificial materials, matrices or substrates that facilitate bridging between functional and non-functional nerve cell tissue.

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Question: Are we providing enough resources in this area?

Answer: The NINCDS appropriation has provided resources to allow maintenance of most of the existing spinal cord research centers and for basic research in neuronal regeneration. Although additional grant applications of high scientific merit were approved but not funded in FY 1985, we believe that progress in this area can be made under the existing funding levels.

Question: Can you estimate the annual economic impact of traumatic spinal cord injury?

Answer: Spinal cord injury occurs primarily in young men in their 20s to 30s, and thus has a major long-term impact on both the victims and their families. Estimates indicate that there are now at least 200,000 survivors of spinal cord injury in the United States and that there are an additional 10,000 new injuries each year. While no dollar value can be placed on the human suffering that accompanies these injuries, it is evident that the economic costs are staggering. Costs of a lifetime of care for a single paraplegic are estimated to exceed $250,000, and the national cost to society for care, lost earnings, and similar expenses is in excess of $2 billion.

Question: What coordination do you have with the National Institute of Handicapped Research in sharing spinal cord research results and in developing research priorities?

Answer: The National Institute of Handicapped Research oversees rehabilitation efforts that are complementary to the basic, applied, and clinical research programs for spinal cord injury sponsored by the NINCDS. The activities of these two national institutes are integrated by frequent staff interactions and coordinated planning in our respective areas. The Director of the NINCDS is a member of the Interagency Advisory Committee of the National Institute of Handicapped Research.

STROKE CENTERS

Question: Last year the Committee included $2 million in additional funds for the NINCDS to support two new Stroke Centers. What steps have you taken to implement these new Centers?

Answer: The NINCDS has received and reviewed meritorious applications for additional stroke research centers. Under the revised 1985 budget, however, it is not likely that any additional new stroke centers will be funded.

Question: The OMB Directive reduces the number of NIH Research Centers by 33 centers (allowing NIH to fund only 500). Will this affect the Stroke Centers?

Answer: In 1985, there are 14 research centers competing for renewal in 1985, six of which are stroke centers. The eight remaining competing renewal research centers are in research areas

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such as Parkinson's disease, acute spinal cord injury, epilepsy, amyotrophic lateral sclerosis, and disorders of hearing and speech. Since several of these competing renewals are being reviewed at the May 1985 National Advisory Council, it is too early to predict the effect on the stroke centers.

NEUROSCIENTIST SHORTAGE

Question: We have been told that due to the rapidly expanding research opportunities in the neurological sciences that the shortage of physician-neuroscientists is becoming critical. What steps is the Institute taking to alleviate this shortage?

Answer: In the early 1970's, the NINCDS began the first NIH program to provide in-depth scientific training to young physicians, the NINCDS Teacher-Investigator Development Award. Though resources were quite limited, particularly in the earlier stages of this program, we know that a large majority of early awardees now hold academic positions as clinician-investigators in U.S. medical schools and have competed successfully for NIH research grant awards. These findings are consistent with the evidence that early exposure to a stimulating research environment is an important element in consideration of an academic research career in the clinical sciences. The Institute is expanding on this principle in two important ways. First, in FY 1983, we enabled some of our most successful research training programs with Institutional National Research Service Awards to provide professional students multiple three-month research training periods with a neuroscientist mentor. This training is offered in an environment where postdoctoral physician research trainees or fellows also serve as role models for the student. Second, in FY 1985, we are launching the new Clinical Investigator Development Award (CIDA) Program which not only encompasses the opportunities available in the earlier awards, but also allows recently graduated physicians to obtain two years of solid research experience in the course of their clinical training. After completion of the program, the CIDA provides salary and research support during a critical three-year period after which the young physician-scientist can be expected to compete sucessfully for independent research support.

Question: What can this Committee do to help?

Answer: The new pilot program of CIDA awards has been enthusiastically received by the scientific community. We currently have 32 applications undergoing initial review and expect, following recommendations from our National Advisory Council, to award the first CIDA in July of this year. We hope eventually to provide these research career development opportunities to approximately 150 physicians. We hope the Committee will support this effort.

CLINICAL TRIALS

Question: As I have said, Congress will support 49 clinical trials in Fiscal Year 1985. Do you have any progress to report in clinical trials supported by your Institute?

Answer: The NINCDS will support 29 clinical trials in 1985.

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Several clinical trials supported by the NINCDS were completed recently, with a number still in progress. The chronic nature of many neurological and communicative disorders requires special clinical trial strategies and long-term followup before definitive answers can be reached. The following are selected examples of recent progress. Guillain-Barre' Syndrome causes sudden paralysis in its victims and follows some cases of viral diseases, including influenza. Scientists in a multi-institution study, sponsored by NINCDS, learned that plasmapheresis, a treatment in which the antibodies in plasma are removed from the blood, greatly speeds recovery. The patients who received plasmapheresis spent less time on respirators, had far shorter hospital stays, and left the hospital in better condition. A study conducted by Dr. Charles D. Bluestone and associates at the University of Pittsburgh, with NINCDS support, showed that decongestant and antihistamine compounds prescribed for a common childhood ear disease called otitis media with effusion are no more effective than a placebo. NINCDS is supporting a major cooperative research study to evaluate the safety and effectiveness of extracranial/intracranial bypass, a surgical procedure designed to reroute blood flow past an obstruction in a blood vessel in the brain and thus preserve function in that area of the brain following a stroke. The eight-year study has followed more than 1,400 patients. Analysis of the data will be completed by June 1985 and will determine the utility of this procedure and appropriate indications for its use. In multiple sclerosis (MS), trials of a synthetic peptide, Copolymer I, are underway with NINCDS support. In the exacerbating-remitting form of MS, a trial has been completed and results will be available in May 1985. Studies of Copolymer I in chronic progressive MS are in progress. Trials of treatments designed to suppress the abnormal immune response in MS are in progress in several institutions, with final data expected in the next year. In epilepsy, several new anticonvulsant drugs are being tested in clinical trials. It is expected that in the next year one or more of these new entities will be adopted by pharmaceutical companies for licensing. A multi-institutional study to test the efficacy of naloxone in acute spinal cord injury has been launched this year.

Question: Are there any trials that are ready to begin in FY 1986?

Answer: There are seven major clinical trials which are ready to begin in 1986.

Question: What are they and why are they important?

Answer: The following is a list of these major trials including a description of their importance.

1. Stroke prevention: medical surgical carotid stenosis study.

   This is a clinical trial to compare medical therapies to surgical and medical interventions to prevent stroke in asymptomatic patients with stenosis or narrowing of the carotid arteries to the brain.

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2. Study of Cyclosporin A for the management of autoimmune disorders such as multiple sclerosis, myasthenia gravis, and Guillain-Barre' syndrome.

   This study is designed to study the efficacy of cyclosporin, a powerful immunosuppressive agent, in the management of selected autoimmune disorders such as multiple sclerosis, myasthenia gravis, and Guillain-Barre' syndrome.

3. Prevention of progression of stroke damage.

   This clinical trial will study the efficacy of drug therapy in limiting and preventing the worsening of stroke damage in the brain following the initial hemorrhage or clot.

4. Diabetes control and complication trial.

   A clinical trial on the efficacy of tight blood glucose control on development of neurological complications of diabetes.

5. Intervention treatment for Amyotrophic Lateral Sclerosis (ALS).

   A clinical trial to study treatment intervention methods for patients with Amyotrophic Lateral Sclerosis.

6. Clinical trial on the treatment of movement disorders.

   A clinical trial to study new agents to ameliorate symptoms in movement disorders such as Tourette's Syndrome and Dystonia. The new agents are dopamine agonists which have been successful in Parkinson's disease.

7. Hyperbaric oxygen in the treatment of multiple sclerosis.

   A clinical trial to study whether or not treatment with hyperbaric oxygen is effective in modifying the symptoms and cause of multiple sclerosis.

Question: Do you have enough funding for these new trials?

Answer: The 1986 budget request does not provide the funds for these major new clinical trials.

BRAIN IMAGING RESEARCH

Question: We have been reading about new imagery techniques such as nuclear magnetic resonance and PET scanning. How does your Institute plan to capitalize on primary areas of research using these techniques?

Answer: Nuclear magnetic resonance or NMR imaging and PET

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scanning are two highly sophisticated methods of examining the living human brain. PET scanning permits the study of brain blood flow, metabolic activity within certain areas of the brain, and neurotransmitter and receptor sites. NMR scanning provides extraordinary details of the structure of the living brain in health and disease. NINCDS plans to capitalize on these areas through its regular research grant program, its specific PET research grant program, and a new initiative for the development of brain imaging research centers. These latter centers would bring together the different imaging methods that demonstrate structure and function of the intact living brain. The centers will use the newest imaging techniques to conduct comparative studies of the brain in health and disease. Each center would be unique, but as a group they will investigate the metabolic activity within the brain, brain anatomy, and brain biochemistry, blood flow, and hydrodynamics. Certain centers would pursue the use of highly specific compounds that permit the detection of receptor sites used for the transmission of information in the normal brain. Others will compare the consumption of glucose and the utilization of oxygen in the brain when it is idling and when it is at work. As we learn more of the normal structure and function of the brain, comparative studies can be undertaken in a wide variety of disease processes, such as stroke, Parkinson's disease, Huntington's disease, epilepsy, deafness, and brain tumors. By understanding the disordered function of the brain associated with these diseases, scientists will be better able to design therapies to prevent the diseases or ameliorate their effects.

Question: Did NIH support play a role in their development?

Answer: The NINCDS has played an important role in the scientific development and assessment of brain imaging methodologies. Seven years ago the NINCDS established its highly productive intramural and extramural positron emission tomography (PET) programs. Now, with the PET research program and the brain imaging centers, the Institute is attempting to develop comparative information about the various imaging methodologies and their strengths, limitations, and differences.

CLINICAL INTRAMURAL STAFF

Question: Many doctors cite the large difference in income between government-supported clinicians and physicians in private practice as the major reason for a shortage of clinicians who perform research. Are there specific intramural programs lacking within your Institute because of this pay discrepancy?

Answer: The IRP has been unsuccessful in recruiting a physician to head up a clinical research effort in Communicative Disorders because salaries and benefits in universities and private practice are substantially higher. For the same reason, we have been unable to recruit ear, nose and throat and electromyography specialists needed for consultation and collaboration with researchers involved in clinical research throughout the NIH. Although we have been successful in recruiting senior resident level neurosurgeons, we have had minimal success in retaining any for permanent tenure because of salary caps at NIH. In the epilepsy

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drug development program, several physician investigators have turned down the vacant position of Branch Chief because of the salary level available.

Question: How much in additional FY 1986 funding would it take to correct this inadequate pay situation?

Answer: Additional funds would not remedy the problem as compensation is limited by the Civil Service pay scales. University salaries and benefits vary, but NIH salaries are generally $20,000 to $40,000 lower than the average university salaries for physician clinical investigators. We currently have 17 tenured medical doctor clinical investigators and seven unfilled senior medical doctor positions.

ANIMAL RESEARCH

Question: What is the NINCDS doing to reduce the use of animals for research purposes and to search for alternative research subjects or models?

Answer: At present, there are no adequate substitutes for experimental animals in spinal cord research. Whenever possible, NINCDS research uses alternatives to animal subjects, such as tissue cultures and computer models. Nevertheless, much of the research sponsored by the NINCDS involves animals. The complexity of the nervous system, the limited time nerve cells can be grown in culture and their inability to replicate, and the lack of reality based data to develop computer models of nervous systems all mandate the use of living animals in neuroscience research. For example, vertebrates are essential for research on spinal cord injury and paralysis because investigators must be able to determine the specific neuroanatomical and neuropathological reasons for the paralysis that follows injury. Scientists study the entire animal as the damage is not just to an individual nerve but to the integrated whole nervous system. Without animal studies, most hypotheses about spinal cord injury, paralysis, and restoration of function cannot be tested outside of man. Animals are used to test therapeutic modalities before they are applied to humans. Such studies provide essential information about tissue responses and possible adverse effects of the potential therapy as well as information on the therapy's impact on the spinal cord injured animal's ability to stand and walk.

Question: What efforts has your Institute made to inform the general public and Congress on the status of this issue?

Answer: As a component of the NIH, the NINCDS does not have a separate policy on the use of animals in biomedical research. The NINCDS participates in NIH and Public Health Service efforts to inform the public and the scientific community about this issue. Several activities are now underway. A revision of the "PHS Policy on Humane Care and Use of Animals by Awardee Institutions" is expected to be issued in April 1985. Also due to be published in April 1985, is a revision of "The NIH Guide for the Care and Use of Laboratory Animals." The National Academy of Sciences, under a contract with the NIH, conducted an evaluation of the relevance and limitations of the use of cell systems, lower organisms, and non-

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biological systems as substitutes for animal subjects in biomedical research. The report of this project is expected to be published in spring, 1985. Plans are proceeding for a multi-phase study by the National Academy of Sciences on the uses of animals in research. In April 1984, the NIH sponsored a national symposium on "Imperatives in Research Animal Use: Scientific Needs and Animal Welfare." A series of regional workshops are planned as a part of this national education effort.

RESEARCH PRIORITIES

Question: Last year your statement advised this Committee that your Institute funds research "that is directly relevant" to approximately 600 discrete neurological and communicative disorders. How does the Institute establish its research priorities, and who is involved in setting these priorities?

Answer: The NINCDS sets its research priorities by recognizing the relationship between scientific opportunity and public need. With the responsibility for research on over 650 disorders, the public need is clearly great. Yet, research priorities must be set where scientific opportunity exists. Spending scarce research funds and energies where there is little chance of critical new knowledge would be imprudent and possibly counterproductive. The members of the scientific and medical research community, as they design research projects and submit grant applications, reflect the cutting edge of science. The eminent scientists from all parts of the Nation, who participate in NIH peer review activities, judge the merits and feasibility of research applications. The members of the National Advisory Neurological and Communicative Disorders and Stroke Council oversee the NINCDS research portfolio and balance scientific opportunity and the need for research in a specific field or disorder. Moreover, the NINCDS Scientific Programs Advisory Committee and the NINCDS Board of Scientific Counselors, each composed of experienced and productive nongovernmental scientists, review the functions and accomplishments of the NINCDS extramural and intramural research programs, respectively. The wishes of Congress reflect the public perception of important health research needs. These insights are a critical component of the priority-setting process. We also learn of public needs through our active relationships with the health voluntary associations that represent specific neurological and communicative disorders, and at professional and scientific meetings.

LONG-TERM PLANNING

Question: Neurology has been identified by you and others as being on the verge of major breakthroughs that will provide greatly expanded research opportunities and significant progress in the treatment of neurological disorders. How will you establish research priorities when opportunities expand and budget growth does not keep pace?

Answer: The process of establishing research priorities does not change during a time of fiscal constraints and expanding opportunities. The NINCDS will continue to set research priorities

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where emerging scientific opportunity and national health needs meet. If fiscal constraints become more severe, a selected few of the most promising projects in the NINCDS intramural and extramural research programs will be supported.

Question: Have you given any thought on how you and the community of scientists that you serve will take your case to the public?

Answer: The NINCDS has an active program to translate research findings and scientific opportunities into terms meaningful to the public. The Institute publishes the "Hope Through Research" series of pamphlets, each describing a specific neurological or communicative disorder, relevant diagnostic and therapeutic information, and new research findings and issues. A series of "Fact Sheets" on specific disorders is also published. These pamphlets are an accurate source of information for many patients with rare neurological disorders and their families. The NINCDS participates in the NIH "Medicine for the Laymen" Series; these lectures present new knowledge on a specific topic to the public in a nontechnical language.

MULTI-INSTITUTIONALLY SUPPORTED RESEARCH PROJECTS

Question: Experimental research suggests that factors such as viruses and the immune system may play significant roles in the expression of many diseases of the nervous system. Has NINCDS initiated any joint research projects with other Institutes within NIH (i.e., NIAID, NCI)?

Answer: The NINCDS coordinates research on neuroimmunology with several other Institutes, including the National Institute of Allergy and Infectious Diseases (NIAID) and the National Cancer Institute (NCI). Intramural scientists from different NIH Institutes frequently collaborate on basic and clinical research projects. To illustrate, intramural scientists from NINCDS and NIAID have particularly strong collaborative relationships in the investigation of the immune response in multiple sclerosis. Scientists from the NIAID and the NINCDS are working jointly on a project entitled, "The Immune Response Against Membrane Antigens." With intramural investigators from NCI, NINCDS scientists are investigating the "Cellular Mechanisms of Lymphoid Cell-Cell Interactions."

In extramural research, grant applications that relate to more than one Institute are assigned to each relevant Institute, with one Institute assigned primary responsibility. The scientist-administrators in each Institute and Division coordinate these projects. For example, the NINCDS and the National Institute of Mental Health (NIMH) are now collaborating on a research project on clinical, genetic, and biochemical aspects of familial Alzheimer's disease.

Other types of coordination also occur. The NINCDS, NCI, and other organizations jointly sponsored the First International Workshop on Neuroimmunomodulation, held on the NIH campus in November 1984. The NINCDS works with other Institutes to encourage

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submissions of research grant applications. For example, the NINCDS and NIAID recently issued a program announcement for research grants on nervous system modulation of immune responses and interactions between nervous and immune systems. Another program announcement, requesting applications for research grants on persistent viral infections and Alzheimer's disease, was recently issued by the NINCDS, the National Institute of Aging, and NIAID.

PREVENTION RESEARCH

Question: In a speech before the American Pharmaceutical Association Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: NINCDS conducts and supports research to understand the normal functions of the nervous system and the sensory organs and the altered mechanisms that lead to neurological and communicative disorders. The overall goal is to discover ways to intercept, as early as possible, the development of the processes that cause neurological and communicative disorders in order to decrease the number of people afflicted with these diseases. The great majority of these disorders are chronic, difficult to diagnose, and have no effective treatment or cure. Hence the focus of much NINCDS research is on the prevention of onset or progression of disease.

This prevention-focused research is designed to identify risk factors, develop methodologies for early detection, and discover and assess biological, environmental, and behavioral methods of intervention in the natural history of these very stubborn disorders.

Listed below are examples of NINCDS research that have the potential of discovering approaches to intercept the early phases of specific neurological and communicative disorders:

- Brain imaging using Positron Emission Tomography (PET) and nuclear magnetic resonance (NMR). PET helps scientists pinpoint metabolic alteration early in the disease process. NMR has great promise for the diagnosis and early detection of neurological disease, especially multiple sclerosis and other diseases of myelin.

- Stroke: The NINCDS supports studies of the nature of stroke and its causes to identify persons at risk, and to prevent the transient ischemic attack or the first full-blown stroke.

- Neurogenetic Inborn Errors of Metabolism: NINCDS conducts research on genetic mechanisms and enzyme studies to detect these disorders before irreversible damage occurs, to identify carriers, to target enzyme therapy, and, ultimately, to correct the genetic deficiency with genetic engineering methods.

- Disorders of Hearing: Studies on the developing ear, the biochemistry of inner ear fluids, genetic aspects of familial

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hearing disorders, inner ear damage from noise, dangerous substances that harm hearing, and middle ear infection preserve hearing or prevent hearing loss.

- Epilepsy: The Institute is supporting research on convulsive disorders designed to identify the various causes of epilepsy and to understand how the disorder begins. These include research to validate effectiveness of drugs to prevent seizures following head trauma.

- Huntington's disease: An international research effort has led to the discovery of a genetic marker on chromosome 4. This discovery should lead to early detection, and, eventually, to appropriate interventions utilizing genetic engineering techniques.

Question: What percent of your budget is directed to preventive research?

Answer: Approximately 12 percent of the NINCDS budget supports research on prevention of neurological and communicative disorders.

Question: How are the results of this research being translated into useful public information?

Answer: Research results are principally transmitted to the public through publications in scientific journals for scientists and health professionals, and in professional and lay magazines for the general public. Also, Institute publications in the "Hope Through Research" series are designed to inform the public about the latest research advances.

MULTIPLE YEAR AWARDS

Question: The OMB Directive requires you to give a number of grants multiple-year awards. How are you going to select which grants will receive this largess?

Answer: Multiple year awards to be made under the OMB Directive will occur later in the fiscal year and the grants which are to receive multi-year funds will be selected based on budget and administrative considerations.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: Costs associated with the administration of NINCDS extramural programs can be reduced through increased utilization of automated office equipment, thereby reducing the need for paper, printing and delivery services. Efforts are currently underway to encourage grant applicants to reduce the size of applications. To the extent possible, meetings of Institute managed Initial Review Groups are arranged to coincide with meetings of national

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professional societies to reduce the travel costs associated with review of applications. Consideration can be given to limiting pre-award site visits to only the largest applications, for example, those in excess of $500,000.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: The NINCDS has a management analysis staff that reviews Institute administrative operations periodically to determine how greater efficiencies in operations or utilization of resources might be achieved. This group has conducted work measurement studies to assure that staffing is appropriate to the workload and studies to identify work processes that are amenable to automation. It has also developed management reports to keep senior Institute management aware of the use of resources.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: A major change has been the installation of an automated local area computer network which permits electronic transfer of documents from one place to another without hard or paper copy. This eliminates much need for reproduction of documents as well as the retyping of whole documents when changes are made. Currently, we are in the process of placing all personnel documents in electronic storage and will soon be able to process all personnel actions electronically. We plan to apply this same technology to as many administrative processes as possible.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: While matters of direct operation are given close scrutiny to assure maximum cost efficiency, there has been no adverse affect on the peer review of research proposals. Project site visits will be made when required, although no particular type of application is automatically assured such a review. Attempts are made to hold meetings in geographic locations which reduce travel costs of reviewers and responsible staff to a minimum.

EPILEPSY RESEARCH

Question: In the Report accompanying last year's Appropriation bill, this Subcommittee expressed concern over the declining share of your Institute's budget which is devoted to epilepsy - the second most prevalent neurological disorder.

Your budget has increased by $159 million or 90 percent since 1978, yet funding for epilepsy research has increased by only $4 million ($16.2 million to $20.2 million). Epilepsy research which totalled 9.1 per cent of your toal budget in 1978 has declined to 6.0 per cent in 1984.

I understand that the Institute has been working with the

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Epilepsy Foundation of America and the American Epilepsy Society on a plan to stimulate more research in epilepsy. Can you explain why epilepsy research has lagged so far behind the Institute's overall rate of growth?

Answer: In the last several years the neurosciences have experienced a remarkable growth not only in new technology, such as neuroimaging, but also in burgeoning new fields such as neuroimmunology. Application of these modern approaches to established research areas, like epilepsy, is now beginning to occur. Although the number of applications received, approved and funded in epilepsy has remained nearly constant, we anticipate that as full advantage of neuroscience advances is taken by investigators in epilepsy, the growth in that area will match other areas in the Institute.

Question: Could you briefly describe the specific activities undertaken by your Institute during the past year to reverse this trend, particularly with reference to clinical research?

Answer: The Institute has used several approaches to increase both the number of high quality applications received from the scientific community, and the interest of the scientific community in pursuing epilepsy research. Specifically, in the past year the Institute has issued two Program Announcements soliciting individual research applications in important areas of epilepsy. The Institute has also publicized its interest in supporting the training of scientists interested in basic or clinical aspects of epilepsy. A new Institute program to train young clinical investigators has been brought specifically to the attention of the epilepsy community to attract new clinical investigators to the field of epilepsy research. Finally, grant supported conferences on specific selected topics have been used by the Institute as a means of stimulating interdisciplinary research in epilepsy. Publications resulting from these conferences serve as state of the art reviews for young neuroscientists.

Question: Despite recent advances in medical treatment, I understand that 200,000 Americans still have more than one seizure a month and over 400,000 have no control over their seizures. I am told that this is due either to insufficient basic knowledge about seizures or in many cases, inappropriate care rendered by professionals who are not treated in the proper clinical management of epilepsy. Is this true, and if so, what can be done to further strengthen clinical research and disseminate its findings?

Answer: Management of seizures which are frequent and/or resistant to medication is an extremely difficult problem, even for experienced neurologists. To assist practitioners, the NINCDS supports not only basic and clinical research on the causes of frequent or resistant seizures, but also an active antiepileptic drug development program aimed at identifying new drugs for difficult-to-control seizures. To disseminate new information, Institute scientists present the results of NINCDS supported studies at scientific meetings, consensus conferences and lectures, and are active participants in continuing medical education symposia sponsored by national and international groups.

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COMPREHENSIVE EPILEPSY RESEARCH AND TRAINING CENTERS

Question : As a means of providing a critical link between basic research and the unmet treatment needs of persons with epilepsy, this Subcommittee urged the Institute to consider establishing Comprehensive Research and Training Centers in last year's Report.

In response to a similar request by the House Appropriations Committee, the Institute submitted a Report evaluating the feasibility of such Centers.

In this Report, the Institute states that it currently supports 11 Multidisciplinary Epilepsy Research Centers. Doctor, how many of these 11 Centers support a substantial effort in both basic and clinical research?

Answer: Of the eleven multidisciplinary epilepsy research centers, four primarily address clinical research problems, four primarily address basic research problems, and three combine both clinical and basic research.

Question: Could you provide for the record a table which allocates between basic and clinical research the total amount of Institute funding during FY 1984 at each of these 11 Centers?

Answer: The following is a list of the multidisciplinary epilepsy research centers with their level of support:

	Basic Research	Clinical Research
1) Epilepsy Research Program Stanford Univ., D.A. Prince, M.D.	$ 478,389	--
2) Neurological Research Center Yale Univ., G.H. Glaser, M.D.	432,869	258,049
3) Minnesota Comprehensive Epilepsy Prog. Univ. of Minnesota, R.J. Gumnit, M.D.	--	877,753
4) Epilepsy Research Center Baylor Univ., P.A. Kellaway	520,636	372,197
5) Epilepsy Research Support Univ. of Wash., A.A. Ward, Jr., M.D., P.A. Schwartzkroin, Ph.D.	662,404	--
6) Center for Clinical Research in Epilepsy Univ. of Wash., A.A. Ward, Jr., M.D.	--	698,461
7) Basic Mechanisms of Seizures Washington Univ., J.A. Ferrendelli, M.D.	469,650	70,828
8) Limbic Epilepsy: A Neurobiologic Approach Duke Univ., J.O. McNamara, M.D.	319,146	--

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9) Neurotransmission and Neurol. Diseases City of Hope, Los Angeles, J.E. Vaughn, Ph.D.	531,687	--
10) Clinical Research Program - Partial Epilepsies UCLA, J.E. Engle, Jr., M.D., Ph.D.	--	489,734
11) Los Angeles Comprehensive Epilepsy Program UCLA, A. Delgado-Escueta	--	1,077,371

Question: The FY 1984 Annual Report of the Convulsive, Developmental and Neuromuscular Disorders Program cites Institute support for 3 Comprehensive Epilepsy Centers. Does this imply that the other 8 Epilepsy Centers cited in your recent report are actually "program projects" and not Comprehensive Centers?

Answer: The designation "Comprehensive Epilepsy Center" serves only to identify the specific research programs supported in response to a 1975 initiative to establish research and training centers in epilepsy. It does not imply a difference in either the basic or clinical research activities between the three centers designated as Comprehensive Epilepsy Centers and the eight other Epilepsy Centers supported by the Institute.

Question: Of the 38 Specialized or Comprehensive Centers which the Justification Document shows were funded during 1984, how many were Epilepsy Centers?

Answer: Five of the 38 were epilepsy research centers.

Question: The Justification Document shows that only 35 Centers will be supported during FY 1985. I understand that the 3 Research Centers which will not be funded are in Epilepsy, Stroke and Amyotrophic Lateral Sclerosis (ALS). Is this information correct and, if so, how was this decision made?

Answer: There are 14 research centers competing for renewal in 1985. They are in research areas such as Parkinson's disease, acute spinal cord injury, epilepsy, amyotrophic lateral sclerosis, and disorders of hearing and speech. Since several of these competing renewals are being reviewed at the May 1985 National Advisory Council, final funding decisions have not been made and it is too early to predict which three of these 14 renewal centers will not be funded under the 1985 adjusted appropriation.

EPILEPSY ADVISORY COMMITTEE

Question: It is my understanding, Doctor, that the charter for the Epilepsy Advisory Committee has not been renewed and therefore, the Committee will terminate on May 31 of this year. Given the apparent problems in funding epilepsy research as documented by the declining Institute support for epilepsy research, what was the rationale behind the decision to terminate the Epilepsy Advisory Committee at this particular time?

Answer: In 1981 the functions of the several extramural

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advisory committees of the NINCDS including the Epilepsy Advisory Committee were consolidated into a single chartered NINCDS Scientific Programs Advisory Committee. Review of NINCDS activities in the field of epilepsy is specifically included within the purview of a chartered subcommittee of the parent committee. As a result, the charter of the Epilepsy Advisory Committee was not extended beyond May 31, 1985.

EPILEPSY BRANCH CHIEF

Question: For almost a year, Doctor, the Epilepsy Branch has been without a permanent Branch Chief. What steps are you taking to fill this position as soon as possible?

Answer: The vacancy was advertised widely throughout the Federal government and nationwide in professional journals. A list of highly qualified individuals was prepared; in depth interviews are being conducted with these individuals to identify a qualified candidate willing to accept the position.

ANTICONVULSANT DRUGS

Question: Are there any new anticonvulsant drugs ready for clinical trials? If so, is the Institute planning to initiate any new clinical trials during FY 1985 or FY 1986?

Answer: In FY 1985, the Antiepileptic Drug Development Program of the Epilepsy Branch, NINCDS identified two promising compounds ready for clinical testing. Pilot studies were initiated on these two new anticonvulsants, one of which will be evaluated in a clinical trial supported by the Institute in FY 1986.

Questions Submitted by Senator Ted Stevens

TOURETTE'S SYNDROME

Question: What research has NINCDS sponsored in the last five years into the rare neurological disorder known as Tourette Syndrome? How does this compare with research efforts on other so-called Orphan Diseases?

Answer: During the last five fiscal years, the NINCDS Intramural Research Program has conducted positron emission tomography (PET) studies on brain function in Tourette's syndrome and begun clinical genetic-epidemiological analyses of Tourette's syndrome patients and their families. Grant support from NINCDS over the past five fiscal years has enabled extramural investigators to pursue Tourette's syndrome studies including clinical genetics, neuroanatomy and neurophysiology of abnormal behaviors, a clinical trial comparing the two drugs pimozide and haloperidol in the treatment of the disorder, and development of new methods for PET scanning in Tourette's syndrome patients.

On some rare diseases, NINCDS supports no directly related research because so little is known about these disorders that formulating intelligent research questions is difficult. However, much of the basic research on the underlying mechanisms of the

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nervous system supported by the NINCDS in areas such as genetics, immunology and pathophysiology is applicable to many rare disorders. For other rare diseases, however, where a conceptual or technological breakthrough has occurred, such as the recently discovered model of Parkinson's disease, more specific research questions can be posed.

ORPHAN DISEASES

Question: How does NINCDS solicit research proposals for Orphan Diseases--please highlight any unique factors that distinguish this process from other research solicitations.

Answer: Most of the 650 diseases within the purview of NINCDS are rare diseases. Through a variety of mechanisms, including workshops on specific disorders, meetings with health voluntary agencies, symposia on the neurobiology of disease, and Program Announcements, NINCDS promotes research on rare diseases. These mechanisms have one fundamental objective: to pull together data from a variety of sources to develop specific research questions which will form the basis for investigator initiated research proposals.

To promote development of therapies for rare diseases, NINCDS participated in the omnibus NIH solicitation for clinical studies of drugs for treatment of rare diseases. In addition, for the last two years, NINCDS has solicited research contract proposals for pre-clinical development of drugs and devices for treatment of rare diseases. The use of the contract mechanism enables the Institute to direct efforts to early phases of drug development in an attempt to stimulate or promote development of new, innovative therapies which might lead to future clinical trials and effective therapies for these rare diseases.

TOURETTE'S SYNDROME

Question: Are there currently any clinical studies of Tourette's syndrome patients at NIH? If not, are there plans for clinical studies in the near future, and if not, why not?

Answer: There are currently three clinical pharmacology studies and one PET study involving Tourette's syndrome. These studies are intended to elucidate the nature of the disorder, its natural history, and to develop improved drug therapies for Tourette's syndrome. A relatively large group of Tourette's syndrome patients is being evaluated by means of the PET neuroimaging techniques. Using these new technologies, local changes in neural functions are being correlated with clinical symptoms including the severity, type, and possible anatomic location of tics. Information acquired from this investigation should help scientists identify the specific neurotransmitter, or neurochemical abnormalities in Tourette's syndrome.

Question: What is the prognosis for expanded research into Tourette's syndrome and related diseases at NINCDS, and what, if any, changes in approach or structure to this research is anticipated?

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Answer: NINCDS has encouraged expanded research into Tourette's syndrome and related diseases through several recent program initiatives. We hope that development of improved pharmacological treatment for Tourette's syndrome patients will result from the Orphan Products Development contract solicitation. Learning disabilities and attention deficits, frequently important symptoms in Tourette's syndrome patients, will be studied in research grants awarded as the result of a Program Announcement concerning brain dysfunction in developmental learning disorders. Moreover, the NINCDS Program Announcement concerning the neurobiology of autism will result in both basic and clinical research on specific behavioral and mental patterns which are also seen in a significant percentage of Tourette's syndrome patients. The Institute anticipates that new approaches to research on Tourette's syndrome will result from recent advances in technology, neuroimaging, which provide expanded research opportunities for delineating brain structure and function in Tourette's syndrome patients and those with related disorders.

Question: A national registry funded by NIH was for Huntington's Disease. Extended families with Huntington's uncovered by this list were the final key to the puzzle: as a result of this registry, the chromosome which causes Huntington's was finally identified. It is my understanding that the computer programs used for the Huntington's registry could be used to try and uncover the Tourette's syndrome chromosome. How much would such a registry cost per year for 8-10 years and has NINCDS given consideration to establishing such a registry for Tourette's syndrome victims and their families?

Answer: A Tourette's syndrome registry would cost about $100,000 per year. NINCDS has had discussions with organizations and investigators interested in establishing a Tourette's syndrome registry to assess the need for such a registry, the research questions it might address and the procedures for submitting research grants to support such an activity.

Questions Submitted by Senator Mark Andrews

POLIO

Question: In the last several months, numerous articles have been written regarding a new polio scare. For many of the estimated 300,000 Americans who were stricken by the disease in the 1950s, polio has once again become a nightmare. Many have written to me and informed me that they are once again suffering from muscle weakness and excruciating pain. Has NINCDS conducted research regarding these problems and what are the plans of NINCDS for further research efforts into this matter, especially for the coming year?

Answer: Yes, the NINCDS Intramural Research Program is studying this problem and attempting to define the cause and natural history of post-polio weakness.

Question: Can you give this Committee an estimate of how many of the 300,000 are suffering from recurring symptoms?

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Answer: Eighty percent of the patients surveyed have new complaints, but the incidence of clinically significant new weakness has not yet been established. So far, our research indicates that the incidence rate is about 15-20 percent.

Question: How many new cases of polio are reported each year?

Answer: About 12 new cases are being reported in the U.S. each year. Outbreaks have occurred in other parts of the world also. Recently there were outbreaks in Taiwan and Finland with about 1500 reported cases.

Questions Submitted by Senator William Proxmire

BATTEN'S DISEASE

Question: Dr. Goldstein, as you know, last year this Committee included language in its report on the Labor-HHS-Education Appropriation bill regarding its expectation that your Institute would continue to support high quality research into Batten's Disease.

The President of "Children's Brain Diseases" wrote me recently to point out that of the four studies you are supporting in this area, one is a general clinical study of children with genetic-metabolic brain disease that has no specific Batten's Disease component, a second focuses on sheep, a third has been turned down for further funding, and only $3,351 has been allocated to the fourth--a study entitled "Inborn Errors of Metabolism of Diverse Etiology." Why isn't the Institute able to do better than that?

Answer: NINCDS support of research in Batten's disease reflects the number of investigator initiated research applications relevant to the area and the assessment of scientific merit by initial peer review groups and the NINCDS Advisory Council. In FY 1985 the Institute funded all three meritorious applications received which were relevant to Batten's disease. However, in addition to research directly related to Batten's disease, the Institute supports a large amount of basic research on the cause and course of those disorders involving inborn errors of metabolism such as that typified by Batten's disease. The Institute has also worked with the voluntary health agencies associated with genetic diseases to encourage additional high quality research applications more directly related to Batten's disease in FY 1986.

ADMINISTRATIVE SAVINGS

Question: Last year you estimated that in fiscal year 1985 you would spend $2,140,000 on rent, communications and utilities. This year that 1985 estimate had dropped to $1,805,000. Can you tell us where the saving of $335,000 occurred?

Answer: The latest estimate reflects a reduction in costs for 1985 rent due to the purchase of office equipment such as word processors and computer terminals which we had been renting.

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Questions Submitted by Senator Quentin N. Burdick

BACK PAIN REPORT

Question: I have received a copy of your report on back pain, prepared at this Subcommittee's request, and I appreciate the work that has been done on this. Does your budget request include money for any of the recommendations listed in this report?

Answer: The NINCDS budget request does not include funds for any of the recommendations listed in the Report on Back Pain.

Question: If you were to prioritize your recommendations, which would you say we should get started on first and how much money would be needed to do it? This is a three-part question and I would assume you may have three different sets of answers, which I would like to see.

Answer: The recommendations all address critical research elements. However, the development of a workable terminology relating to back pain, the refining and enlarging the data base for back pain in the United States, and perfecting methods to quantify more accurately the back pain experience would all be prerequisites to more complex clinical studies. The initial first year expenditure would require $1.8 million.

Question: In addition, what would be your "wish list" in this area and, for contrast, what do you think we could realistically get done in the coming year? This is a three-part question and I would assume you may have three different sets of answers, which I would like to see.

Answer: The next most important studies to undertake would be those necessary for a more fundamental understanding of back pain; these studies will be significantly more time-consuming. Such studies would include identification of pain receptors and spinal cord and brain pathway mechanisms involved in the perception of back pain, delineation of the pathways of endorphins, or neurochemicals that halt pain, and investigation of reflex mechanisms involved in back pain. For some of these studies, newer methods would have to be developed and appropriate laboratories established. Clinical studies, which almost always require considerable developmental and implementation time, could have the initial phases started during the coming year. If the $4 million required for these high priority items listed above were available, these studies could be initiated but certainly not completed during the coming year.

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NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

STATEMENT OF DR. ANTHONY S. FAUCI, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. BERNARD TALBOT, DEPUTY DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. Next we will hear from Dr. Anthony Fauci, the new Director of the National Institute of Allergy and Infectious Diseases.

The Institute is requesting a budget that is $19 million below last year's appropriated level of $371 million.

Allergic and infectious diseases account for nearly one-third of all patient visits to physicians' offices. Along with drug therapy, these visits account for costs in excess of $4.5 billion annually. And that figure doesn't take into account the cost of lost wages and productivity.

Dr. Fauci, I welcome you to the committee. Your predecessor at the Institute of Allergy and Infectious Diseases was always well received in these rooms and elsewhere. We are looking forward to working with you, why don't you please proceed.

Dr. FAUCI. Thank you, Mr. Chairman, and Senator Proxmire.

I have submitted my written comments for the record, and I would like to spend a minute or two outlining and highlighting for you two areas that are of particular interest and importance to the mission of our Institute, and discussing the recent advances that have occurred over the past years in these two areas.

[The statement follows:]

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Statement of Dr. Anthony S. Fauci

The human body has always been, is now, and always will be the target of a relentless series of assaults from without as well as within. Infectious microorganisms pose the greatest external threat. The enemy is highly sophisticated, clever by any standards, and constantly adapting to the body's attempts to protect and heal itself. Our survival depends upon a complex and, until recently, inscrutable system of defense mechanisms in the form of our immune system. Indeed, the immune system can be considered the body's "defense department."

The immune system is, in fact, an organ system and, like any other organ system in the body, such as the cardiovascular, nervous, and endocrine systems, is subject to failure and dysfunction. The immune system can be nonspecifically overwhelmed or even specifically attacked by invading infectious microorganisms. It can be defective at birth, leaving the body partially or even totally vulnerable to infectious agents. On the other hand, the immune system can often be difficult to control in that it is so finely tuned and its defenses so sharp that it can sometimes wrongly identify its own tissues as a foreign invader and react against itself, as it does in autoimmune disorders such as systemic lupus erythematosus and rheumatoid arthritis. Likewise, it often mounts an inappropriate response against generally harmless substances such as in asthma, hayfever, and other allergic reactions.

The job of researchers supported by the National Institute of Allergy and Infectious Diseases (NIAID) is to discover why the body's defenses are disrupted and how this can be corrected and prevented. Our research is aimed at characterizing at the molecular level the microorganisms responsible for infectious diseases; at restoring the immune system that has been overcome by infectious agents or immunological defects; at enhancing the system by immunization; at modifying its function, as in the case of prevention of organ transplantation rejection; and at correcting its malfunction in asthma and other allergic and autoimmune disorders.

The immune system is a distinct organ system intimately connected with the mission of our Institute. It is also the focus of the basic science of immunology, which has had over recent years significant impact on the study of disease processes involving other organ systems. Basic research on this organ system has provided extraordinary insight into areas such as cell cloning, molecular biology, and hybridoma technology. Appreciation of the inseparable link between basic and applied research on the immune system was shown in the choices for the Nobel Prize in Physiology or Medicine in 1984, which was shared by three immunologists. Two of them received their share of the award for developing the methodology of hybridomas that produce monoclonal antibodies in virtually unlimited quantities. This technology has led to a revolution in the diagnosis, prevention, and treatment of a large number of diseases that overlap all medical specialities. The third awardee was honored for his extraordinary contribution to the theoretical and conceptual aspects of immunology. In giving these awards, the Nobel committee clearly recognized the importance of these dual paths of investigation -- basic and applied research.

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NIAID continues to assign high priority to conducting and supporting research in basic and clinical immunology and allergy. Asthma and allergies constitute major health problems affecting an estimated 40 million Americans at a cost of approximately $4 billion per year. Our Institute supports 13 Asthma and Allergic Disease Centers and 5 Centers for Interdisciplinary Research in Immunological Diseases. I will mention only one of the many important research advances in this area.

Five years ago, the chemical structure of one of the leukotrienes, important clinical mediators of inflammation, was discovered, leading to a Nobel Prize. This work reflected years of NIAID-supported research. It is now recognized that these compounds are by far the most potent known stimulators of muscle contraction and mucus secretion. Thus, we think that we may have in hand a major cause of the airway obstruction that occurs in asthma. Moreover, because the synthetic pathways are already understood, a number of pharmacologic agents capable of preventing leukotriene formation or its effects have been developed and are already being tested in humans.

The incredible progress that scientists have made during this century in understanding how the immune system works to protect us against infectious diseases has resulted in dramatic improvements in life expectancy and in the quality of life. The reason for our success in avoiding serious infectious diseases, particularly childhood infections, lies largely in vaccination, our major method of disease prevention. This committee has heard previously about NIAID's Program for Accelerated Development of New Vaccines. Of five vaccines assigned high priority for the United States by an Institute of Medicine committee, one is already undergoing expanded field trials. This is the live, cold-adapted influenza vaccine. Three others should be licensed within one to three years. These include Hemophilus influenzae type b, which can cause meningitis and other severe infections in young children; varicella, the virus of chickenpox, which can cause devastating disease in immunosuppressed children such as those with leukemia who are receiving chemotherapy; and a new hepatitis B vaccine, which has resulted from an intensified exploitation of recombinant DNA technology. Several vaccines against diarrheal diseases for international use have advanced to field trials. These include cholera, typhoid, and rotavirus. The latter is of particular importance, as diarrhea is the leading cause of infant deaths worldwide, and researchers have identified the rotaviruses as major causes of diarrhea in children throughout the world. Finally, exciting progress is being made in developing vaccines for malaria.

NIAID is the major supporter of tropical disease research in the United States. The reasons for this are many. A significant portion of the world's population (including Americans who work in Third World countries) are affected by "tropical diseases," usually caused by parasites. Malaria causes disease in about 300 million persons, schistosomiasis in 200 million, and filariasis in 175 million. In awareness of the enormity of this problem, we have increased NIAID support for International Collaboration in Infectious Disease Research and for tropical disease research units in the United States.

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NIAID-supported researchers are exploring several approaches in the development of malaria vaccine, including a new genetic engineering technique developed this year by NIAID scientists. Vaccines have been and are being developed against various stages in the parasite's life cycle. A new and potentially important approach has been the development of a vaccine that elicits antibodies that are carried over to the mosquito during a bite and block parasite fertilization within the mosquito, thus interrupting subsequent transmissions. Finally, genes coding for one, or conceivably all, of the stage-specific antigens of the parasite could be incorporated into a hybrid vaccinia virus which has been developed on our Bethesda campus and which may, in fact, revolutionize vaccination techniques. Our commitment to international medicine is strong. Such research is scientifically important, knowledge gained from it will ultimately help directly or indirectly our own citizens, and it is a sure way to demonstrate to the world that Americans are compassionate and respectful of life throughout the world.

Here at home, our Institute is concerned with developing vaccines and therapies as well as improved methods of diagnosis for the growing problem of sexually transmitted diseases (STDs). STDs cause enormous human suffering and place a heavy burden on medical care facilities. In FY 1983 alone, STDs cost the American public an estimated $2 billion. Gonorrhea, genital herpes, and chlamydial infections have reached epidemic proportions. Despite considerable progress in this area, there is a continuing need for further research, particularly with regard to the development of vaccines and of new and improved therapeutic antiviral drugs.

Now I must turn to a disease that I know all too well, in that I have spent a major component of my own personal basic and clinical research effort in its study. The acquired immunodeficiency syndrome (AIDS) is truly an enormous health, economic, and social problem with implications for all Americans. As of March 1985, AIDS in its full-scale form has afflicted approximately 8,500 Americans with a mortality rate that surely will approach 100 percent. Last year at this time, we did not know the cause of this deadly disease. Researchers at the NIH and abroad have now isolated and characterized the causative virus, HTLV-III/LAV. It is most extraordinary that the etiologic agent has been discovered only three short years after the disease was recognized. This is a perfect example of how ongoing research in diverse and seemingly unrelated areas can come together to solve a mysterious and devastating disease. I had already been involved for 15 years in studying the regulation of the human immune response at the time AIDS became recognized.

AIDS is a disease that devastates the immune system in a most unique and specific way. Patients with AIDS have a profound and selective depletion of a subpopulation of immune competent cells called helper T lymphocytes, which are responsible for the orchestration of the entire immune response in man. Using knowledge we had gained over the years of basic research on the immune system, we quickly determined that the helper T cell was the specific target of the then hypothetical infectious agent, thus providing a major clue to its identity.

Dr. Robert Gallo of the National Cancer Institute had already made enormous contributions to understanding the role of viruses in

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cancers which affect the immune system with his discovery of HTLV-I as the first virus recognized to directly cause a tumor in man, incidentally a tumor characterized by a malignant proliferation of helper T cells. Could it be possible that a similar virus caused AIDS? The answer is yes, and the rest is medical history.

I must add a word of caution: the fight against AIDS is far from won. We have a diagnostic test for HTLV-III/LAV that will enable blood banks to screen the nation's blood donor pool and ensure the safety of transfusions. However, we have no effective treatment or prevention. We must develop chemotherapeutic agents that directly inhibit the virus. NIAID is heavily involved in this area of research as well as in the area of vaccine development against the retrovirus and in broad studies on the natural history of the disease. We continue to explore avenues for reconstitution of the immune system. We are developing and testing therapies directed against the many opportunistic infections in AIDS; some of these results have been extremely encouraging and will have important implications in the treatment of these infections in non-AIDS patients. Furthermore, our precise delineation of the effect of this virus on the immune system has already paid substantial dividends. This knowledge has proved invaluable in our dissection of the complexities of the immune system and in understanding its role as a defender against outside invaders as well as against the development of cancers.

I firmly believe that this disease is one of the most serious ever to afflict mankind. It is transmissible (sexually and via blood or blood products), it is currently untreatable, and it is lethal. We owe an energetic, well-supported effort against AIDS to the populations at highest risk and to the American people as a whole since recent evidence strongly points to the conclusion that the disease can and is spread in the United States not only by homosexual transmission but also by heterosexual contact, similar to its spread in Central Africa. This will almost surely lead to increasing appearance of the disease among individuals not considered to be within the classic high-risk groups.

Mr. Chairman, the 1986 budget request for this Institute is $352,561,000, a decrease of $15,353,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants funded. Specifically, in 1985 this Institute will fund 431 new and competing grants of which 59 will receive 3 years of support.

I will be happy to answer any questions.

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Biography of Dr. Anthony S. Fauci

December 24, 1940. Brooklyn, New York

Education:

College of the Holy Cross, 1962 - A.B.; Cornell University Medical College, 1966 - M.D.

Professional History:

1966-1967, Intern, Department of Medicine, New York Hospital - Cornell Medical Center. 1967-1968, Assistant Resident, Department of Medicine, New York Hospital - Cornell Medical Center. 1968-1970, Clinical Associate, Laboratory of Clinical Investigation, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Bethesda, Maryland. 1970-1971, Senior Staff Fellow, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1971-1972, Chief Resident, Department of Medicine, New York Hospital - Cornell Medical Center; Instructor in Medicine, Cornell Medical College. 1972-1974, Senior Investigator, Laboratory Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1972-present, Consultant in Infectious Diseases, The National Naval Medical Center, Bethesda, Maryland. 1974-1980, Head, Clinical Physiology Section, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1977-1984, Deputy Clinical Director, NIAID, NIH, Bethesda, Maryland. 1980-present, Chief, Laboratory of Immunoregulation, NIAID, NIH, Bethesda, Maryland. 1984-present, Clinical Professor, Department of Medicine, Division of Rheumatolgy, Immunology, and Allergy, Georgetown University School of Medicine, Washington, D.C., 1984-present, Director, NIAID, NIH, Bethesda, Maryland.

Board Certification and Military Service:

American Board of Internal Medicine - June 21, 1972. American Board of Allergy and Immunology - March 1, 1974. American Board of Infectious Diseases - October 15, 1974. U.S. Public Health Service, July 1968-June 1970; July 1972-present.

Professional Organizations:

American Federation for Clinical Research, American Association for the Advancement of Science, American Association of Immunologists, Fellow, of The American Academy of Allergy, Infectious Diseases Society of America, American Society for Clinical Investigation, Fellow of the The American College of Physicians, Association of American Physicians, Collegium Internationale Allergologicum.

Offices Held:

Councillor, Eastern Section, American Federation for Clinical Research (AFCR), 1977. National Councillor, AFCR, 1978-1979. President, AFCR, 1980-1981.

Advisory Boards and Committees:

Chairman, Allergy and Immunology Committee, MKSAP V, American

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College of Physicians. Advisory Panel, The American Board of Medical Laboratory Immunology. Member, Committee on Clinical Immunology and Immunopathology, American Association of Immunologists, 1980-1985 Representative of American Association of Immunologists to the Examinations Committee of the American Board of Allergy and Immunology, 1981-present. Postgraduate Education Committee, American Academy of Allergy, 1979-1982. Member, NIAID Study Group on Immunology, 1980. Member, Section on Physiology in Clinical Science of the American Physiological Society, 1980-1984. Member, Subcommittee on the Classification of Vasculitis, American Rheumatism Association, 1980-present. Subcommittee on Clinical Sciences, Publications Committee, American Physiological Society, 1980-1984. Program Chairman, Group for AIDS, 1982-present. Member, American Federation for Clinical Board of Directors, American Board of Allergy and Immunology, 1984-present. Participant in the USA - People's Republic of China Immunology Immunology Cooperative Agreement, August 10-22, 1983, Beijing and Shanghai, PRC. Member, Scientific Advisory Board, Medical Biology Institute, La Jolla, CA, 1983-1984. Participant in the USA-Japan Eye Immunology Advisory Conference, November 27 to December 1, 1983, Honolulu, HI. Member, External Advisory Committee, Multi-purpose Arthritis Center, Duke University Medical Center, 1984-present. Member, Honorary Advisory Board, Italian-American Medical Association, 1984-present. Member, Peripatetic Club, 1984-present. Ex Officio Member, National Diabetes Advisory Board, 1984-present. Ex Officio Member, National Digestive Diseases Advisory Board, 1984-present. Chairman, Search Committee for Director, National Institute of Child Health and Human Development, 1984-present. Member, Department of Health and Human Services Task Force on Alzheimer's Diseases. The 1985 Albert Lasker Medical Research Award Jury.

Editorial Boards:

Dr. Fauci has been or is on the Editorial Board of 21 scientific journals in the field of immunology, allergy and infectious diseases. These include: The Journal of Clinical Investigation; The Journal of Immunology; Journal of Infectious Diseases; Journal of Clinical Immunology. Dr. Fauci is also the Editor of one of two major textbooks of medicine in the world, "Harrison's Principles of Internal Medicine."

Awards and Honors:

Alpha Omega Alpha. Kileen Prize for Excellence in Chemistry (College of the Holy Cross). John Metcalfe Polk Prize for General Efficiency (Cornell University Medical College). Alfred Mortitz Michaelis Prize for Efficiency in General Medicine (Cornell University Medical College). U.S. Public Health Service Meritorious Service Award. 1979. Arthus S. Flemming Award, 1979 - Given to the 10 outstanding employees in the U.S. Federal Government. Squibb Award of the Infectious Diseases Society of America, 1983. U.S. Public Health Service Distinguished Service Medal, Professor of Medicine at a large number of major medical schools throughout the country.

Publications:

Dr. Fauci has authored over 450 scientific publications in the field of basic and clinical immunology and infectious diseases.

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AIDS

Dr. FAUCI. You have heard much about the disease called the acquired immunodeficiency syndrome, AIDS. The agent responsible for this disease has been isolated recently and characterized by Dr. Gallo of the National Cancer Institute.

As you know from past hearings, the National Institute of Allergy and Infectious Diseases is interested in infectious diseases, allergies, and other diseases of the immune system. With AIDS, we have an extremely unusual situation of an infectious disease, in this case a virus, that specifically and selectively infects the immune system and renders it incompetent to perform its function of protecting against infections and tumors.

Our approach over the past year has been to take this virus, which has been isolated recently, and extrapolate the most recent advances in molecular biology to clone and characterize the virus, and essentially break it down into its genetic components for the purpose of characterizing its functional capabilities.

This has led, over the past year, to our ability to improve diagnostic capabilities, and has opened the door for efforts aimed at development of a vaccine. More importantly, for the mission of the NIAID, it has allowed us to delineate quite clearly the effect of this virus on the immune system. The implications of this are great because of our interest in the role of the immune system, not only in AIDS, but in a number of other diseases which are characterized by abnormalities of immune function.

And so, by studying a syndrome that is a disease of the immune system, we have learned a considerable amount about the workings of the immune system, and at the same time, we have made significant strides in understanding the disease itself.

MALARIA RESEARCH

Another disease that is of great importance in the world today is malaria. There are 300 million individuals in the world who are infected with malaria each year, and this causes 1 million deaths per year, usually among children less than 5 years old.

The difficulty with malaria is that previous attempts to eliminate this disease by removing the mosquito vector or by treating the disease with drugs directed at killing the parasite have not proven to be entirely successful.

An important area of research in malaria has been that of vaccination. However, a major stumbling block in the vaccination approach to malaria has been the lack of ready availability of the parasite itself for study. Up until most recently, there were not sufficient quantities of malaria parasite antigens available to produce a vaccine so that one could inoculate or immunize vast numbers of people.

Here again investigators turned to molecular biology, and were able to take one phase of the life cycle of the parasite, extract the genes from that phase, and then pick out the one gene that was responsible for coding for the protein that will ultimately serve as our vaccine.

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That gene was then incorporated into bacteria, and essentially instructed that bacteria to make unlimited quantities of that protein which, in fact, will be our vaccine. The most interesting and important aspect about this whole story is from the time we had the genes cloned to the time we had the vaccine available for phase I clinical trial was an unprecedented 18 months, something that we have never seen before in vaccine development. Of note is the fact that this has occurred in a disease of great importance worldwide.

This concludes my remarks; I will be happy to answer any questions you may have.

MALARIA VACCINE

Senator WEICKER. Let me pick up right there. This vaccine, this malaria vaccine, this will be available in larger quantities when?

Dr. FAUCI. We have done testing in animal models, and it looks promising. It is effective in protecting animals. This year we will start what we call phase I trials to determine whether it is safe to give to humans. Phase I trials usually take about a year or so. I imagine that within the next few years, we will have a vaccine that will be suitable for a large clinical trial.

Senator WEICKER. What is the funding for this particular phase of your operation, particularly in the overall budget?

Dr. FAUCI. With regard to our malaria vaccine development, specifically, it is approximately $600,000. The malaria vaccine work itself is also based on a large basic science base that allowed us, for example, to use the molecular biological approach. There is $600,000, specifically, targeted for malaria research, but there are a lot of other basic resources that are indirectly involved in this project.

Senator WEICKER. What was it last year?

Dr. FAUCI. If one talks about just malaria vaccine development research, Mr. Chairman, the figure which I gave you was for that. If we are talking about all studies on the disease, the total for that would be $4.8 million.

What I just presented to you was the fruit of what has gone on last year and the year before.

Senator WEICKER. About $600,000. Would an increase in funding in that particular area accelerate the production and availability of this vaccine?

Dr. FAUCI. At the present time, we are not at the stage to speak in terms of availability versus lack of availability for widespread use. We have made a major first step. When the phase I clinical trials are completed, and we know that the vaccine is, in fact, safe and ultimately efficacious, a major push will be necessary at that time to make the vaccine available for mass production and wide distribution.

Senator WEICKER. Dr. Wyngaarden, would you be good enough to take a look at this particular item and make sure that nothing can be done vis-a-vis its acceleration?

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Dr. WYNGAARDEN. We will do that.

DPT VACCINE

Senator WEICKER. If I ever had to go in and explain that there is only $600,000 for something that potentially could save a million lives * * *.

There are two items that I would like to inquire about, the controversy that seems to be revolving around DPT, if you would put that into perspective for me, give your views as to that, where do we stand on that?

Dr. FAUCI. Mr. Chairman, first of all, I might say that the controversy lies around the pertussis component of the DPT vaccine. Pertussis vaccine as it has been used for 40 years in this country is quite an effective vaccine. It has some toxic side effects. Most recently there has been increased awareness of these real and potential side effects.

In this country, we are still using what we call the whole cell vaccine. The difficulty with the whole cell vaccine is that there are multiple different components of it, some of which one can have a reaction to, resulting in some of these toxic effects.

The ideal situation would be to get what is called an acellular vaccine. This product is already being used in Japan, and it has been shown to be, at least from noncontrolled widespread use, effective and safe.

Our goals and directions with regard to pertussis vaccine research over the next year are several. One is to develop our own acellular pertussis vaccine. In this regard, we have awarded a contract to the Michigan Department of Public Health, to undertake that task. In addition, a commercial firm in the U.S.A. will take the Japanese acellular pertussis vaccine, and under an IND in this country, will repackage it with tetanus and diptheria, and undertake clinical trials with it. We are also now gearing up for conducting clinical trials using the acellular vaccine in Sweden.

There is a difficulty with doing a clinical trial with a new pertussis vaccine in our country. One might ask, why do you not take the acellular vaccine and start using it now in this country? The difficulty is that in a country like ours where the incidence of whooping cough or pertussis is so low, you really cannot do an effective clinical trial. Since the vaccine which is currently employed in this country is so effective in preventing disease, it would not be acceptable to discontinue completely or partially its use to compare it with a vaccine whose efficacy has not yet been formally proven. Therefore, you have to test the new vaccine in a country in which they are either not vaccinating or are currently employing a vaccine which is not particularly effective. Once you have proven the efficacy of the new vaccine, only then could you substitute it for the currently used vaccine, provided the new vaccine has also proven to be safe.

In summary, we are developing a better vaccine. Work is in progress, and we are gearing up to test the acellular vaccine in a country where the study would be appropriate.

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REYE'S SYNDROME

Senator WEICKER. Your comments relative to the matter of Reye's syndrome.

Dr. FAUCI. With regard to Reye's syndrome, we have been for some time now emphasizing and studying the role of viral infections, such as the influenza virus on the etiology and the pathogenesis of the disease. It has been rather well established that there is an association between certain viral infections, predominantly following influenza B, and the development of Reye's syndrome. In addition, a number of other relatively common viral infections have been implicated.

As I am sure you are well aware, there has been increasing evidence that there is also an association with the use of aspirin, particularly during the convalescent stage of the viral infection, and the development of Reye's syndrome. We have been involved in such studies, and now there is rather clear-cut evidence that there is an association.

What we are gratified to see now is an increased awareness and acceptance on the part of certain aspirin manufacturers, and there has been a willingness to make a warning available on labels that, in fact, when a child does have a respiratory infection, there is the possibility of impending complications if one does use aspirin.

I think that there has been real progress, both scientifically as well as in public awareness.

Senator WEICKER. Let me ask something as an interested parent. When you say, aspirin, you are being very specific in using that as a word of art as compared to, let's say, Datril, Tylenol, and that other group.

Dr. FAUCI. Yes; aspirin or acetyl salicylic acid.

Senator WEICKER. Senator Proxmire.

SPREAD OF AIDS

Senator PROXMIRE. Dr. Fauci, on page 7 of your prepared statement, you refer to AIDS as one of the most serious diseases ever to afflict mankind and go on to say that evidence strongly points to the conclusion that the disease is being spread by heterosexual contact and blood transfusions as well as homosexual contact.

Can you give us a rough estimate of how many Americans carry the AIDS virus now and indicate the extent to which the virus may spread over the next 5 to 10 years?

Dr. FAUCI. The availability now of the test for antibodies to the AIDS virus will shortly give us an idea of the number of individuals that have been exposed to and may still be infected with the virus. As you have heard in testimony yesterday, this does not tell you whether you have the disease or not; it only tells you whether you have been exposed to or infected with the virus.

If one looks at the figures that are now being accumulated from natural history studies, right now, today, in the third week in March, we have close to 9,000 cases of what we call full-blown AIDS.

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Senator PROXMIRE. This disease is growing at a geometrical rate, isn't it?

Dr. FAUCI. The number of reported cases is doubling approximately every 8 months to 1 year.

Senator PROXMIRE. It is a sentence of death. You say that fatalities approach 100 percent.

Dr. FAUCI. One must be careful because the terminology is frequently not appreciated by the lay public. When we are talking about the full-blown disease, we mean that an individual already has sufficient suppression of the body's defenses that he or she either has one of those opportunistic infections or Kaposi's sarcoma. In those patients with full-blown AIDS, the mortality at this particular point in time is likely 100 percent.

We are not entirely certain about the prognosis of those individuals who have been infected with the AIDS virus but who have not yet advanced to the point of having such disruption of their immune system that they are at high risk for these opportunistic infections and/or tumors. It is very unclear what their ultimate prognosis will be.

However, we do have some preliminary data concerning the risk of developing full-blown AIDS among individuals who have a positive antibody test. Studies in this country and in Scandinavia indicate that at least 10 percent of those individuals will develop the full-blown disease, and likely as high as 20 to 27 percent.

If one then extrapolates these figures to the number of individuals who might be projected to be positive for antibodies, I think that this is where you get the number that you have been reading about in the paper, the approximately 40,000 individuals who might be developing the full-blown disease in the next couple of years.

Senator PROXMIRE. Can you give us some idea of the extent to which AIDS might spread over the next 5 to 10 years?

Dr. FAUCI. It really depends upon the scientific progress that is made, but not completely, because even though we might make vast advances scientifically, it does not necessarily mean that we are going to be controlling completely the disease; but it is at least a first step.

A lot will depend on whether we develop a vaccine that is effective, and here again that is a big if, Senator Proxmire. You heard from Dr. DeVita yesterday that there is already a vaccine that is at least testable in animal models. It is, of course, uncertain at present whether it is going to be effective. If a vaccine, in fact, is available and testable, and proven to be efficacious in humans, then I think that you could see a sharp drop in the number of cases. In addition, public health measures to educate the risk group regarding the transmissibility of the disease will also have an effect in reducing the incidence of AIDS.

Areas that are of great interest to our Institute, and in which we are collaborating with the NCI, are treatments directed against the AIDS virus. In summary, there are at least three or four things going on simultaneously that are going to have a major impact on the control of AIDS.

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Senator PROXMIRE. All of this work, of course, will require substantial funding.

Dr. FAUCI. All of them are ongoing.

Senator PROXMIRE. Many who carry the virus apparently do not contract AIDS. Do you know of any factors that predispose individuals to this disease?

Dr. FAUCI. There are no definite factors that have been proven by controlled studies to be predisposing factors, but we do know, for example, if individuals are exposed to the virus by homosexual or heterosexual contact, that other infections that they might have may predispose them by already perturbing their immune system. We know that from certain *in vitro* studies. If you take a lymphocyte which is the target of this virus, and you throw the virus into the test tube, that lymphocyte is generally refractory to infection. If you activate that lymphocyte, or infect it with another virus, it is much easier for that lymphocyte to get infected with the AIDS virus.

If you can extrapolate that to the clinical situation *in vivo*, then one would think that certain underlying infections, such as those that the male homosexual population have, would predispose them. But the bottom line is that you have to be exposed to the AIDS virus in order to get AIDS.

COST OF TREATMENT FOR AIDS

Senator PROXMIRE. How much will the treatment of AIDS cost this country over the next few years?

Dr. FAUCI. It has been estimated that the cost for an individual who has the full-blown disease is anywhere from as low as $50,000 or as nigh as $100,000 per person. If you multiply that by the 9,000 cases we have now, and the acceleration of cases that will occur, you are talking about a substantial amount of health care costs.

Senator PROXMIRE. The disease is doubling every 9 months.

Dr. FAUCI. Yes.

Senator PROXMIRE. Thank you.

Thank you, Mr. Chairman.

Senator WEICKER. We will be taking a careful look at this.

What I intend to do, Dr. Wyngaarden, after I have heard from all of your directors, first of all, we can take it as a given that if I can get the votes on the committee, I will be countering the administration's budget. I would like you to put your heads together and figure out the areas of greatest importance, so that it is not just my imposing layman's terms. I would appreciate such items coming from you, and it will be up to me to work things out with the administration. Rather than applying a layman's judgment to what is important and what is not, I am asking you to furnish us with information as to what you consider the most important areas. It could very well be that I will be voted down in the committee, but I doubt it, so that will be helpful.

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I have many further questions, but I must confess to being very impressed with your testimony. I look forward to working with you. Thank you very much. There will be further questions for response to the record.

Dr. FAUCI. Thank you, Mr. Chairman.

Senator WEICKER. Dr. Löe, I didn't mean to leave you out. The information that you gave us yesterday on that herpes vaccine, that was very important.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

VACCINES

Question: You have indicated that you have targeted 10 diseases for vaccine development or vaccine improvement in the next decade. Can you identify which diseases, and tell us how far along you are in the development of vaccines?

Answer: The National Institute of Allergy and Infectious Diseases (NIAID) had previously targeted the following 10 diseases or groups of diseases of national and/or international importance for prevention by immunization within the next 10 years:

- Meningitis
  - *Haemophilus influenzae*, type b (Hib)
  - Group B streptococci
- Gonorrhea
- Croup and pneumonia in infants and children
  - Parainfluenza viruses
  - Respiratory syncytial virus
- Whooping cough (*Bordetella pertussis*)
- Influenza
- Diarrhea
  - Cholera
  - Dysentery
  - Typhoid
  - Rotaviruses
- Hepatitis
  - Type A
  - Type B (second generation)
- Chickenpox (varicella virus)
- Genital herpes
- Malaria

In 1986 high priority will be assigned to development of a vaccine for the Acquired Immunodeficiency Syndrome (AIDS) and the five diseases selected by the Institute of Medicine (IOM) (Vol. I, Diseases of Importance in the United States; New Vaccine Development - Establishing Priorities):

- Hepatitis B virus (HBV, recombinant DNA-derived)
- Respiratory syncytial virus (RSV, live attenuated)
- *Haemophilus influenzae*, type b
- Influenza (live attenuated)
- Varicella (immunocompromised children)

Of the five vaccines assigned high priority by IOM, three (HBV, Hib, varcella) should be licensed within the next 2 years, one (influenza) is undergoing expanded field trials, and the fifth (RSV) has been advanced by recent basic studies.

A detailed progress report on all ten disease categories is contained immediately following the questions submitted for the record.

Question: Are you receiving adequate funding for this effort? If not, how much more is necessary?

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Answer: In 1985, we estimate obligating about $11,846,000 for the Accelerated Development of New Vaccines Program; our estimate is $11,932,000 for 1986. With this amount, the program will be maintained at an acceptable level. However, we have identified the following projects that could be undertaken if additional funds were available:

- Efficacy trial of new, second-generation hepatitis B vaccines. This trial could be carried out in the Peoples Republic of China under the U.S.-China Bilateral Science Agreement. (First-year cost, $150,000)

- An efficacy trial of a malaria vaccine prepared from the sporozoites of Plasmodium falciparum which causes the most virulent form of malaria in humans. (First-year cost, $600,000)

- An extension of trials using a chickenpox vaccine, now known to prevent the disease in immunosuppressed children, to prevent the occurrence of zoster in older people. (First-year cost, $838,000)

- Various gonococcal antigens other than those currently being studied as potential vaccine materials; for example, gonococcal lipopolysaccharide and Proteins II and III of gonococcal outer membrane. (First-year cost, $500,000)

- Efficacy trials of rhesus rotavirus vaccine to prevent severe diarrhea: one trial in U.S. urban, middle-class children and one in urban, lower-class children. (First-year cost, $700,000)

- Use of new biotechnologies to produce vaccines for respiratory syncytial and parainfluenza viruses. (First-year cost, $500,000)

Question: If you are successful in bringing these vaccines to the American public, what magnitude of cost savings would we be talking about?

Answer: The IOM study is being carried out in two phases, one for vaccines for domestic use and one for vaccines for international use. The IOM has just recently completed the first phase which provides NIAID quantitative estimates of the costs of vaccine preventable illnesses and annualized present values of expected net costs for vaccine development. The first phase of the IOM study provides estimates for nine of the disease areas. The second phase will also provide estimates for malaria and diarrheal diseases (as related to international use). The IOM study shows that the total cost to the United States for the vaccine preventable illnesses concerned with the nine disease areas is $5.7 billion annually. Given the magnitude of the problem with malaria and diarrheal diseases, it is clear that enormous savings would result in the international area when these diseases could be effectively prevented. Estimates for these two disease areas will be contained in Vol. II of the IOM study.

Question: Does that include treatment and productivity?

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Answer: The annualized present value of expected net costs used by the IOM includes the annualized vaccination program costs, the annualized cost of vaccine development, and the preventable treatment costs. It does not include the indirect cost (productivity, etc.), savings that would add to the annualized savings. The IOM model does include estimates for cost of treatment. Taking the top two examples that predominately affect children, varicella in high-risk individuals and respiratory syncytial virus, the IOM report shows an expected annualized present value of expected net savings of $75 million.

DPT VACCINE

Question: There has been a great deal of concern expressed about the dangers of the DPT vaccine given to young children. Can you put this concern into perspective and tell us what is being done to improve the vaccine?

Answer: In the United States, 50 percent of pertussis cases occur in the first year of life. For this reason, pertussis vaccine, as DPT, is administered beginning at 2 months of age. At this age, young infants may also experience such other illnesses as febrile convulsions, the onset of epilepsy, infantile spasms, and sudden infant death syndrome, providing a background of events that may be associated in time with the administration of vaccine. Fever and systemic symptoms are more common following DPT than following vaccine without pertussis (DT). In the National Childhood Encephalopathy Study in England, the attributable risk estimate for a serious acute neurologic disorder within 7 days after DPT vaccine was one in 110,000 doses and for a permanent neurologic deficit was one in 310,000 doses. Postulating that these adverse reactions may be due to components of the whole cell pertussis vaccine that are not essential for protection, investigators are developing acellular vaccines containing only "essential" antigens.

Steady progress has been made in the development of an improved pertussis vaccine since the International Symposium on Pertussis held at the National Institutes of Health in November 1978. Progress prior to that date is reflected in the reports presented at that conference. The current whole cell vaccine that has been so effective in preventing whooping cough contains multiple antigenic components derived from Bordetella pertussis. Which component, or combination of components, induces resistance to infection and disease is not known. Similarly, which component, or combination of components, is responsible for the adverse reactions attributed to the vaccine is not known. Because the bacterial products contained in the vaccine can now be isolated, purified, and characterized, it has become possible to quantitate the amount of each in acellular vaccines, and to eliminate undesired components such as endotoxin.

American and Japanese scientists have focused on two components, pertussis toxin (PT) and filamentous hemagglutinin (FHA). Japanese firms have produced vaccines containing varying amounts of these two antigens and, more recently, a vaccine consisting principally of PT. None of these vaccines has been subjected to strictly controlled efficacy trials in children of the age group immunized in the United States. A Japanese acellular pertussis vaccine imported by Wyeth Laboratories for use in making

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DPT has been tested in 4- to 6-year-old and 6- and 18-month-old children in NIAID-supported vaccine evaluation centers and is now being tested in 2-, 4-, and 6-month-old infants. This vaccine should soon be available for an efficacy trial.

Of three other commercial firms, one, Connaught Laboratories, has a well defined PT/FHA vaccine ready for testing in the NIAID vaccine evaluation centers; negotiations are now in progress to add this to the clinical efficacy trial in Stockholm proposed in collaboration between the PHS and the National Bacteriology Laboratory of Sweden. Sweden has experienced epidemics of whooping cough since it discontinued use of an ineffective pertussis vaccine, and the United States will take this opportunity to collaborate with Swedish investigators to test the efficacy of one or more acellular vaccines. Serological studies will be done in connection with the trial in Stockholm to determine which antibodies to which antigens correlate with immunity.

The National Institute of Child Health and Human Development has developed a vaccine consisting solely of toxoided PT and proposes to test this vaccine at yet another site in Sweden. Thus, at least three candidate vaccines are nearly ready for Phase I testing in young children and will need to be subjected to efficacy trials within the next year. While studies of these "second generation" acellular vaccines are in progress, studies will continue to develop "third generation" vaccines using recombinant DNA technology to express or to synthesize the one or more antigens determined to be essential for immunization.

Question: Senator Hawkins has introduced a bill that would create a Federal compensation fund for victims of vaccine-caused injury. How can we identify with certainty vaccine-caused injury?

Answer: It is difficult to identify vaccine-caused injury with certainty. Local reactions such as soreness and redness at the site of injection and the simultaneous occurrence of fever may logically be attributed to the vaccine. Other events occurring within 30 days include allergic reactions, arthritis/arthralgia, convulsions, encephalitis/encephalopathy, and paralysis (from live poliovirus vaccine). Since all these events also occur in the absence of immunization, each case must be carefully examined.

Question: What is your view of this bill in light of the fact that threat by litigation has reduced the number of vaccine manufacturers to one?

Answer: With regard to Senator Hawkins' recently introduced vaccination compensation legislation (S.827), the Cabinet Council on Human Resources has an established working group on vaccination compensation. This group is currently examining this legislation in view of the fact that threat by litigation has reduced the number of vaccine manufacturers. The Council is expected to make its recommendation to the Secretary, DHHS shortly. It would be premature for me to offer an opinion at this time.

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INFLUENZA EPIDEMIC

Question: Dr. Fauci, recent reports from the public health authorities indicate that we are experiencing a significant influenza epidemic this winter. What research is the NIAID doing in this area?

Answer: Influenza is an extremely important public health problem--certainly one of the most important that we face. This winter provides ample evidence of the impact of influenza in the United States. Outbreaks have been reported from all areas of the country; some have been severe. It is certain that excess mortality will be reported. The NIAID is committed to continue its research activities in this area to provide improved methods of prevention, diagnosis, and treatment. We have been very active in this area in recent years. First, we have continued research and development of improved vaccines for influenza. We are very encouraged with the new live, attenuated influenza vaccine. This vaccine, called the cold-adapted (ca) vaccine, was developed by Dr. H. F. Maassab at the University of Michigan and has been shown to be stable, attenuated, and immunogenic. Field trials with this vaccine are underway, and we plan to begin a comparative field trial of the ca vaccine and current inactivated vaccines this year. Although results to date are encouraging, many problems still remain that will take time to solve. For example, we do not have a ca vaccine for the type B influenza viruses. Two candidates are now under development, but it will take several years before we know which of these ca vaccine donors is best and if the B vaccines can be used in combination with the type A viruses. Finally, clinical trials to demonstrate that these vaccines are efficacious will take time.

Our efforts are not limited to vaccine development. During the last 10 years we have successfully tested two antiviral compounds, amantadine and rimantadine, which are effective in the treatment and prevention of influenza type A virus infections. We plan to initiate a trial of the efficacy of these antiviral drugs in the treatment of severe influenza infections, particularly in the high-risk populations--the elderly and patients with chronic lung or heart disease. Influenza type B infections remain a problem in this regard, but antivirals with broader spectrum of activity are under development which inhibit these viruses.

Question: Is there any promise that influenza can be prevented in the future?

Answer: Ultimately, answers to the influenza problem require support for not only the studies described above, but also for basic research on influenza. The NIAID will continue to support research on the basic properties of influenza viruses. These research projects will enable investigators to develop more effective antiviral drugs or vaccines. A better understanding of the complex epidemiology of these viruses is also an important priority in influenza research. As we learn more about how these viruses circulate in nature, we will be able to better predict which variants are likely to produce epidemics in man.

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REYE SYNDROME

Question: Testimony received last year about Reye Syndrome indicated it was still a mystery. Recently, the producers of children's aspirin have agreed to warn parents that the use of aspirin in high fever situations may contribute to contracting this syndrome. Has research confirmed that aspirin may be associated with the development of Reye Syndrome?

Answer: Two years ago the Assistant Secretary for Health established the Public Health Service Reye Syndrome Task Force (PHSRSTF) to conduct a study to examine the association of medication use with the development of Reye Syndrome. The membership of the PHSRSTF includes representatives from the FDA, CDC and NIH. The PHSRSTF, with the advice and assistance of an advisory group selected by the Institute of Medicine (IOM) and the National Academy of Sciences, designed an epidemiological study to examine this question. This study, now in its second year, seeks to compare the medication usage in children who develop the disease with four different control groups--children who attend the same school, children who live in the same area, children admitted to a hospital for treatment, and children seen in emergency rooms. The IOM recommended that the study be conducted in two phases. The first phase was to be a pilot study during which the methods to be used in the main study were to be tested. This phase was completed in December, and the second phase of the study is now underway. The pilot study was a field test of the protocol for the main part of the study. Thirty children with Reye Syndrome and 145 matched control children were studied. The analysis of the data obtained during the pilot phase suggests that the use of aspirin was associated with the development of Reye Syndrome. The odds ratio that a case was exposed to salicylates was significantly higher than for all four control groups. This finding is consistent with the findings of four earlier studies. These data were reviewed by the Institute of Medicine Advisory Committee in December. The IOM Committee recommended that the main study be performed, that the results of the pilot study be published, and that the DHHS take the necessary steps to protect the public health.

Question: Has any progress been made in the last year?

Answer: Based on the above, it is clear that significant progress has been made in the last 18 months. Once the main study is completed, it should be possible to determine the validity of the association of aspirin or salicylate-containing medications with Reye Syndrome. A report of the results of the pilot study has been submitted for publication.

TROPICAL MEDICINE

Question: I have had discussions with your predecessor, Dr. Krause, about research in tropical medicine and more specifically, malaria. Staff informs me that you may be close to developing a vaccine for malaria. Can you tell us about this?

Answer: Several approaches to the development of a malaria vaccine are underway. Vaccines have been and are being developed against various stages in the parasite's life cycle. The most

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advanced is the production of a synthetic vaccine which protects against the sporozoite form of the parasite transmitted by the mosquito. Initial testing of this vaccine will probably begin later this year. The second approach to a malaria vaccine is directed toward the asexual stage. DNA sequence analysis has allowed production of peptides that cause the generation of specific antibody. An exciting new approach to the control of malaria has been the development of a vaccine that elicits antibodies in the host, which are taken up by the mosquito during a bite and which block fertilization of the parasite within the mosquito, thus interrupting subsequent transmissions. Finally, genes coding for one, or conceivably all, of the stage-specific antigens could be incorporated into a hybrid vaccinia virus.

Question: What do you, as director, see as the priority for research in tropical medicine?

Answer: Tropical diseases affect close to a billion residents of the tropical areas throughout the world as well as many Americans who work or travel in endemic tropical areas. Many of these diseases are caused by parasites responsible for high morbidity and mortality rates. Malaria is found in about 300 million persons, with schistosomiasis being present in 200 million, followed by filariasis infecting over 175 million. It is important to note that the NIAID is the only significant organization in the world with a primary commitment to support meritorious free-ranging research in immunology and microbiology related to tropical diseases including very basic research on parasites or host responses. Particularly in view of the current explosion of new knowledge and rapid research advances in basic immunology and the prospects for vaccine development, a major priority must be to continue support of these research efforts that are the cornerstone for the application of this knowledge to the treatment and prevention of these diseases by other agencies such as USAID or WHO. In addition, we must do everything we can to facilitate the dissemination of research advances in these diseases to the developing world.

More specifically, as mentioned previously, NIAID has identified malaria and diarrheal diseases including typhoid, dysentery, rotavirus infections, and cholera as diseases targeted within our Accelerated Development of New Vaccines Program for prevention by new and/or improved vaccines.

AIDS

Question: Your Institute is playing a major role in the AIDS research efforts. Where do we stand in respect to developing a treatment for this disease?

Answer: Research on the development of treatment methods for the acquired immunodeficiency syndrome (AIDS) focuses primarily in two areas: the development of effective antiviral agents that will attack the AIDS retrovirus directly and the use of various immunomodulators or transplantation procedures for reconstituting the defective immune system. The ultimate treatment for this disease will probably involve a combination of antiviral agents and procedures for restoring the immune deficiency.

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With regard to antiviral treatment, NIAID scientists in a collaborative project with the NCI have administered suramin to seven patients. The results from this study are very preliminary, but they are encouraging, and additional patients will be treated with this drug. Extension of the suramin studies and the initiation of ribavirin studies are beginning at the NIAID. As other antiviral agents become available, they will also be evaluated.

Several approaches have been used at the NIAID to reverse the underlying immune defect caused by the AIDS retrovirus. NIAID scientists along with other NIH colleagues are attempting to enhance immune function with immunomodulators such as gamma interferon and interleukin-2. At the present time, interferon appears to be quite toxic at levels needed to have an effect on the immune system; therefore, it does not appear to be a feasible therapeutic agent for AIDS.

Thirty-five patients have been studied using a naturally produced or recombinant interleukin-2. Interleukin-2 treatment resulted in increased lymphocyte count, appearance or enhancement of delayed cutaneous hypersensitivity response, and amplification of natural killer cell activity. While there is some toxicity, it appears to be at an acceptable level. No clinical response in the patients' illness was seen, but these immunological responses give encouragement that the use of interleukin-2 in conjunction with an effective antiviral agent could be useful in treatment.

In a unique effort to reconstitute the immune system of an AIDS patient who had a healthy identical twin, Dr. Clifford Lane and I combined techniques of repeated adoptive transfer of lymphocytes with bone marrow transplantation. Although the patient died and the ultimate goal of the study was not met, definite improvement in the patient's immune function was clearly documented.

While we do not have a combination of an antiviral agent and a mechanism for reconstituting the immune system which has yet been shown to cure AIDS, research along this line shows promise; and it is hoped that a successful combination will be developed.

NIAID is also supporting a number of contracts to develop better treatments for the opportunistic infections that affect AIDS patients.

Question: Anything new in the area of vaccine development now that Dr. Gallo of the Cancer Institute has identified the virus causing AIDS?

Answer: The discovery by Dr. Gallo of the NCI of the causal agent of AIDS has led to progress being made on various approaches to vaccine development. The NCI, at the present time, has the most extensive program. Since vaccine preparations containing nucleic acid are considered undesirable, the NCI is not pursuing the approach of using a whole inactivated vaccine. The Institute is, however, using a subunit approach. The whole virus is being fragmented and the envelope components, free of nucleic acid, are being studied to determine which subunits represent the best candidate antigens. These fractions can be tested as possible vaccines, and the genetic code for these antigenic subunits can be

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derived and the antigen produced through recombinant DNA technology The NCI expects to have candidate subunit vaccines available for testing in nonhuman primates in the very near future. The NIAID will collaborate with the NCI in future clinical studies of candidate vaccine preparations that have proved safe and antigenic in animal studies.

In addition, the NIAID has cloned the AIDS retrovirus and has several genes under consideration for possible vaccine development efforts. We are also collaborating with NCI in attempts to insert an appropriate HTLV-III envelope gene into vaccinia virus that will then serve as candidate AIDS vaccine. The NIAID approach may also lead to the development of synthetic vaccine candidates.

We see some potential problems in these approaches to vaccine development. For example, the external glycoprotein product of the virus envelope that is being considered as a candidate vaccine is very fragile, and it may not be stable enough to be a useful vaccine. In addition, the virus appears to be heterogeneous, and there may be a number of antigenic variants of this virus. Hopefully, there will be some cross reactive antigens common to all the variants which can be used as candidate vaccine preparations.

Question: Please describe the functions of the AIDS Coordinating Group at NIH and how it relates to your Institute's research in this area.

Answer: The primary NIH coordinating group is the AIDS Executive Committee chaired by Dr. Wyngaarden, the Director of NIH. The membership of the Executive Committee includes relevant NIH staff members and senior staff members from NCI, NHLBI, and NIAID. In addition to the overall Executive Committee, there are subcommittees with responsibility for particular areas. One such subcommittee with relevance to the mission of the NIAID is the Subcommittee on Animal Models, Vaccine, and Therapeutic Modalities. The committee and subcommittee meet on a regular basis and, as needed, consider particular questions or problems. The committees coordinate research efforts of the various Institutes as well as provide frequent opportunities for information exchange on research activities. Discussions within these committees have an influence on research directions so that maximal cooperation is obtained and unnecessary overlap is avoided. There is also a PHS Task Force on AIDS whose membership includes the Heads of all concerned PHS agencies.

Question: What is the funding level for intramural research on AIDS in the NIAID?

Answer: It is estimated that our Intramural Research Program will obligate $7,736,000 in 1985 and $7,241,000 in 1986 to further research in AIDS.

Question: Do you think you could effectively use increased funds for AIDS research in the 1986 budget? How much more would you need?

Answer: This area is emerging rapidly and we are continually reassessing resource requirements for AIDS research. As science

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breakthroughs materialize, additional resources may be required. At the request of the Assistant Secretary for Health, we have undertaken a very recent reassessment of AIDS research findings and areas of promise. The Secretary has promised to keep the Subcommittee informed of any changes in resource needs.

BONE MARROW TRANSPLANTATION

Question: We understand how bone marrow transplantation may be used to restore deficient elements in immunodeficiency disease. Are there recent scientific advances that show promise for making bone marrow transplantation useful in other disorders as well?

Answer: Replacement of the recipient's deficient cells with immunocompetent donor bone marrow continues to be one of the major procedures for treatment of immunodeficiency diseases. Bone marrow transplantation is also the preferred treatment for aplastic anemia and certain kinds of leukemia and may offer an avenue for treatment of other diseases. For example, a patient with sickle cell anemia who received a bone marrow graft for unrelated reasons from her tissue antigen-matched brother was cured of her sickle cell disease. Bone marrow transplantation has also been utilized in cases of thallasemia (Cooley's anemia). In addition, there have been several cases of genetic enzymatic deficiencies which respond to bone marrow transplantation. In these cases, individuals who do not have the gene which codes for a particular enzyme, or whose gene codes for a deficient enzyme, can receive bone marrow cells from a genetically normal donor. If these cells divide and repopulate the marrow, the recipient is capable of producing enzyme normally. One can see the potential for curing a wide variety of genetic deficiency diseases in this way.

Because of the broad potential for treatment of devastating diseases with the use of bone marrow transplantation, it is important to actively pursue ways of improving this technique. Treating bone marrow with monoclonal antibodies against various subgroups of immunocompetent cells in order to avoid graft-versus-host disease has been used successfully. Improved techniques of donor/recipient matching have also made bone marrow transplantation from unrelated donors possible. Modern immunosuppression techniques have made grafts from partially matched, related donors a reality. It is certain that potential applications for bone marrow transplantation will increase substantially over the next several years.

PREVENTION RESEARCH

Question: It would seem that a great deal of your research focus would be in the area of prevention of infectious diseases. Other than the work being done in the development of vaccines, what are your efforts in prevention research?

Answer: Although our major emphasis is on vaccines, we do support efforts in some other approaches for preventing infectious diseases. These other approaches include: passive immunization by specific immune globulins; chemoprophylaxis through the use of drugs such as amantadine for influenza and acyclovir for genital herpes; the control of vectors by biological and chemical means; control of

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the environment through the identification of infectious agents and limitation of their spread; and prompt diagnosis and early treatment to prevent secondary spread and late complications.

Question: Do you feel that this effort should be expanded, and if so, what level of funding are we talking about?

Answer: At this time I think that the NIAID prevention research efforts are properly balanced between vaccine research and development activities and other approaches for the prevention of infectious diseases.

FULL TIME EQUIVALENTS (FTEs)

Question: I note that you are reducing the level of full time equivalents (FTEs) in the intramural research program by 34 under the FY 1984 levels. These FTEs are program staff, not administrative--am I correct?

Answer: Yes, the FTE reduction involves program staff, which includes professional, technical, and clerical personnel.

Question: How does that affect the intramural research program? I would like to hear specific examples.

Answer: In response to the Secretary's announcement that AIDS is a national health emergency with top priority, NIAID has assumed a major responsibility for conducting AIDS research over the past two fiscal years. The NIAID intramural program has developed research programs in several areas considered essential to the understanding of the epidemiology, immunology, and etiology of AIDS and the prevention and treatment of this syndrome. Due to the high priority and scientific interest in this disease, significant efforts were taken at the outset to redeploy a considerable number of existing positions from other research projects, and also to postpone recruitments for other non-AIDS related positions. As the momentum and importance of subsequent research findings dictated, we felt compelled to create new positions without position ceiling increases in order to maintain an effective level of AIDS research support and collaboration in the areas of animal models, epidemiology, immunomodulation, vaccine development, and treatment. Because FTEs have been redirected away from other high priority research areas into AIDS, intramural projects in tropical medicine, vaccine development, organ transplantation, and sexually transmitted diseases have been especially affected. The further reductions in 1986 will necessitate a decrease in the number of young investigators brought to the NIH campus for the purpose of enhancing their training. Technical and clerical support available to scientific staff in the areas of allergy, infectious, and tropical diseases will also be reduced.

DISCRETIONARY FUNDING OF RESEARCH

Question: How much discretionary power do you have as the Director of a categorical research Institute to fund research that may not be in line with the priority set by the Institute's National Advisory Council?

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Answer: I would say that I have adequate discretionary power to support research that is within our mission but may not have been specifically addressed within the overall priorities recommended by our National Advisory Council. If research opportunities are identified and require accelerated or greater emphasis in a particular area, we can accomplish this by soliciting research through Program Announcements and Requests for Applications for grants or Requests for Proposals for R&D contracts. Furthermore, the Institute employs a process whereby grants that fall beyond the established payline are recommended to Council for "selective payment." In this way we can respond to existing plans or to changes in plans resulting from the identification of new research areas or areas of increased importance or public health need. In a new or particularly fast moving field, resources can often be mobilized most quickly in the Intramural program. This was the case with AIDS, where the first research was conducted intramurally, later followed by extramural efforts.

Question: What criteria do you use to apply that discretionary power?

Answer: The key issue involves the identification of research opportunities and public health need. In setting priorities for research, we employ a number of mechanisms. First, of course, we rely on our National Advisory Council as well as three other chartered public advisory committees including our Board of Scientific Counselors, the Microbiology and Infectious Diseases Research Committee, and the Allergy, Immunology, and Transplantation Research Committee. We also convene scientific/expert task forces that render state-of-the-science assessments and identify the attending research opportunities in specific areas. Within the Institute, there is close and frequent communication between me and my Program Directors who closely cooperate with the scientific communities corresponding to their areas of speciality. Furthermore, Institute staff and I participate in the deliberations of the scientific community through attendance at conferences and workshops and at meetings of constituent professional organizations. This interaction enables me to rapidly identify new areas of research or to perceive the need for changes in program emphasis.

Question: What value does this power have in guiding the Institute's research efforts?

Answer: The power and flexibility to direct and/or divert resources is particularly valuable in terms of reacting to a new or fast moving field where a quick response is important. For example, it allowed NIAID to begin studying AIDS quickly after it first appeared and has permitted us to shift research emphasis in this field as advances dictate. Likewise, we will be able to develop quick responses to any future public health emergencies or to new problems or new issues within our purview.

INTRAMURAL RESEARCH PROGRAM PRIORITY

Question: How is research priority set for your Institute's intramural program?

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Answer: Research priorities of the intramural program of the NIAID are set by Institute leadership including the NIAID Director, the Scientific Director of the Intramural Research Program, and the Chiefs of the 13 laboratories within the intramural program. Many factors are taken into consideration in setting research priorities. These factors include: the professional judgment of Institute leadership on what the highest priority research areas should be, the expertise available within the institute staff, the personal research interests of institute scientific staff, advice from outside advisory groups such as the National Advisory Allergy and Infectious Diseases Council and the NIAID Board of Scientific Counselors, as well as direction from the Public Health Service, the Department, and the Congress.

Question: Is there a formal review process set up to decide what research will be funded through the intramural program?

Answer: There is no formal process equivalent to that in extramural programs for initiation of projects. The decision to conduct a specific research project depends upon the interest and expertise of individual investigators in consultation with and approval by the Laboratory Chief. The Laboratory Chief takes into consideration the overall needs of his laboratory, possible overlap with other research activities in NIAID and NIH, and the funding situation for his particular laboratory when making decisions on new projects. Each research project in the intramural program is submitted as a written proposal in a specific format for review and approval by the Scientific Director. A project number is assigned for reporting and administrative purposes. While the approval of an outside peer review group such as the NIAID Board of Scientific Counselors is not required for the initiation of a research project, the Board of Scientific Counselors monitors each ongoing intramural research project and provides advice to the Scientific Director and Institute Director on the quality of each project and investigator and the relevance and value of the research.

Question: How do you monitor ongoing programs?

Answer: Ongoing research programs are monitored continually by the individual Laboratory Chief and the Scientific Director. Once a year, an annual report of each intramural project is prepared and submitted to the Scientific Director for review and approval and then forwarded to the Institute Director for similar action. In addition, in order to ensure that the quality of intramural research is equal to that of research supported through the extramural programs, the NIAID has a chartered advisory committee for the Intramural Research Program. This committee, the NIAID Board of Scientific Counselors, consists of eight eminent scientists from outside the NIH. The Board meets twice a year to review the work of one or more laboratories (depending upon the size). At each meeting of the Board of Scientific Counselors, ad hoc consultants are added to provide adequate manpower and expertise to review the particular laboratory. Each intramural scientist is interviewed by Board members and/or ad hoc consultants, and his/her research project is carefully evaluated for its quality and relevance. A written report on the research of the laboratory together with appropriate recommendations are submitted to the Scientific Director, Institute Director, and NIH Deputy Director for Intramural Research. With a

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meeting schedule of twice a year, each of the 13 NIAID intramural laboratories is reviewed every third year. This coincides approximately with the review periods that an outside grantee would receive for continuation of his funding. We feel that the standards applied to intramural research projects by our Board of Scientific Counselors is on the level with that applied to research grant applications and that this strict and careful review allows us to maintain the highest quality intramural research.

SALARY LEVELS

Question: Has NIAID had any difficulty attracting and maintaining qualified senior scientists in your intramural research program?

Answer: Most of the senior scientific staff within the NIAID Intramural Research Program have been developed within the program. Most began as staff fellows or medical staff fellows and have remained, as their careers developed, to become tenured staff scientists. There have been a few cases of senior staff scientists being recruited from outside of NIH, but this is the exception rather than the rule. Keeping well-known, established scientific investigators within the intramural program is a problem; fortunately, however, many excellent people elect to forego better salaries on the outside for the unique research atmosphere provided by the NIH.

Question: Has salary level been a problem in this regard?

Answer: Salary level is clearly a problem in the retention of top quality scientists. Those who have heavy financial responsibilities for family reasons (e.g., educational expenses) have been forced to leave the government, accepting salaries often two or three times the maximum salary that they could receive at the NIH. Again, because of the unique research opportunities at NIH, many excellent researchers have chosen, at great financial sacrifice, to stay at NIH.

Question: How many such scientists have you lost because of insufficient salary levels?

Answer: It would be very difficult to quantitate the scientists that have been lost because of comparatively low government salaries. In most cases in which senior scientists have left the NIH, they have gone into excellent academic and industrial positions that not only pay well, but present good career opportunities. The question of salary and personal finances is usually a private decision and is rarely the reason given by a scientist for resignation. In my own personal experience, I am aware of a number of staff members from our Institute who, for financial considerations, have been forced to leave government service.

PREVENTIVE RESEARCH

Question: In a speech before the American Pharmaceutical Association Dr. Wyngaarden said that 28 percent of NIH funds are

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directed to preventive research. What types of preventive research are being done by your Institute?

Answer: The NIAID has an interest in prevention research applicable to the two broad areas of medicine and science we support. We include in our prevention portfolio projects that fit the following categories:

I. Prevention of Infectious Diseases

A. Active Immunization
B. Passive Immunization
C. Chemoprophylaxis
D. Control of Vectors
E. Control of Environment
F. Prompt Diagnosis and Early Treatment

II. Prevention of Immunologically Mediated Diseases

A. Asthma and Other Allergies
B. Immunodeficiency Diseases
C. Autoimmune Diseases
D. Immunogenetic Disorders

Question: What percent of your budget is directed to preventive research?

Answer: In 1984, prevention research represented 15.7 percent of the NIAID total actual obligations. Similar percentages are expected in 1985 and 1986.

Question: How are the results of this research being translated into useful public information?

Answer: The results of the NIAID prevention research endeavors are predominantly such that they are used in medical practice by physicians or public health workers and are not dependent on modification of personal behavior by members of the public; e.g., cessation of smoking or diet modification. In addition to the usual release of research results through reports in the scientific and medical literature and at scientific meetings, our Institute staff members interact with professional societies and special interest lay groups who help disseminate recent results. Staff also participate widely in workshops, conferences, interviews with both the print and broadcast media, and in the various activities of the NIAID Office of Research Reporting and Public Response.

In addition, our Centers for Interdisciplinary Research on Immunologic Diseases program has enabled institutional groups of investigators to develop programs aimed at the clinical application of health research data and educational projects for physicians, allied health professionals, patients, and health consumers. A well-attended symposium on vaccines at Georgetown University is an example of such an educational effort.

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TRAINING

Question: The research career program is being reduced from 80 in 1984 to 73 in your FY 1986 request. How important is this program to your Institute and why is it being reduced?

Answer: While the Institute places a great deal of importance on its research career program, we continue to place primary emphasis on investigator-initiated research project grants which are so vital to the ultimate development of new concepts, new tools, and new knowledge for the treatment and prevention of disease. In doing this, it is necessary to reduce the level of support for other mechanisms such as the research career program.

Question: You have also reduced your training programs from 494 in 1984 to 464 in FY 1985. Why?

Answer: The reason for the reduction in the number of trainees to be supported in 1985 is due, in part, to the decision to provide all trainees with a much needed stipend increase and to the fact that we supported significantly more training positions in 1984 than originally estimated.

OMB EFFECT ON CONTINUING GRANTS

Question: I note that you are planning to reduce the number of continuing grants by 52. How will the 52 be chosen?

Answer: The 52 grants will be chosen primarily by priority score. Under the 1985 appropriation, we estimated awarding about 211 competing renewal research project grants. For the September Council, this meant supporting all competing renewal research project grants with a priority score of approximately 160 or better, and a few with scores higher than 160 that were recommended by Council for "selective payment." Under the 1985 current estimate, we would make about 159 competing renewal research project grant awards. At the January Council this resulted in the support of all competing renewal research project grants with a priority score of approximately 140 or better, and a few with scores higher than 140 which were recommended by Council for "selective payment." The same would hold for the May Council.

Question: Research that is ongoing and successful enough to qualify for continued support is being stopped. What is the effect of such action on the scientist involved?

Answer: The effect of interrupted support for a successful and deserving research scientist often is devastating from the standpoint of the scientist himself, his technical staff, fellows, graduate students, and the research. On occasion, research teams may have to be disbanded. Unless the investigator is very senior and has tenure at his university, his job and the possibility of consideration for tenure may depend upon his ability to obtain and keep outside grant support. In most cases, his technicians are supported entirely through his grant funding and consequently must find other employment--obviously, a problem for them and a set back to the research project. In addition, graduate students and fellows studying with an investigator are usually supported through his

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grants, and their training can be interrupted. There are, however, a number of sources of interim support available to investigators who loose their grant award. These funds may be provided by the investigator for a short period during which time the investigator can seek to redirect the work or otherwise improve his application to be more competitive in subsequent review periods.

Question: How much money already invested will be lost in these cases:

Answer: Only after our next Council meeting, in May 1985, will we know precisely which grants will comprise the 52 cases; and only at that time will we be able to retrospectively total how much money was previously invested in the projects. Since research is continuously producing information in the form of data, new hypotheses, etc., it is not necessarily the case that the investment in these projects will have been lost.

Question: Can you provide us with an example of the effects of this action?

Answer: Three examples of competing research project grants which would have been funded under the 1985 appropriation, and may not be funded under the 1985 current estimate are:

A project that has been supported for the past 9 years at a total cost of $666,967--This applicant requests to continue investigations into the parameters of immunity to varicella zoster virus (VZV or chickenpox) infection. The dissection of the immune response to VZV is very important because current patient management of seronegative children with malignancies who are known to be exposed to VZV depends on an accurate determination of the immune status of the patient. As such, this research activity complements the clinical trial of VZV vaccine and strengthens the study significantly. In addition, the possibility of using the VZV vaccine as a method of preventing shingles in adults is currently being explored. The success of such a study will depend on the development of reliable methods of determining the immune status of an individual.

Work that has been supported for the past 13 years at a total cost of $1,499,658--One of the most prominent researchers in the field of immunodeficiency diseases was recommended very highly by the initial peer review group for a 5-year renewal of award. The applicant proposed to continue efforts defining the influence of inherited and induced enzyme abnormalities on immune function. The reviewers noted the excellent record of progress and publications during the prior period of support and agreed that the proposed studies have a high probability of success.

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A project that has been supported for the past 6 years at a total cost of $430,984. This proposal is for investigations seeking to understand the pathogenesis of Neisseria gonorrhoeae, the microorganism causing gonorrhea. The reviewers characterized this as a strong proposal and gave it an excellent priority score. The principal investigator's objective is to study the role of the components of the outer membrane of the gonococcal cell, the process the gonococci use for entering human cells, and their viability and growth in such human cells in a cell culture system. It should be understood that there is absolutely no animal model for studying gonococcal infections, short of man himself, so that tissue or organ culture of human cells are the only means of investigating the virulence factors and pathogenic mechanisms of this microorganism.

OMB

Question: The OMB Directive reduced the number of new and continuing grants in your Institute by 132. How was that number arrived at?

Answer: Indeed, in 1985 the number of new and competing renewal research project grants estimated to be funded was reduced from 563 to 431, a decrease of 132 grants. This was our pro rata share of the overall NIH reduction.

Question: How are decisions being made as to where to make the cuts?

Answer: As with competing renewal grants, all competing grants will be chosen primarily by priority score. Under the 1985 appropriation, we estimated awarding about 563 competing research project grants. Thus, at the September Council, we identified for payment all competing research project grants with a priority score of approximately 160 or better, and a few with scores higher than 160 that were recommended by Council for "selective payment." Under the 1985 current estimate, we will award about 431 competing research project grants. This results in the award of all competing research project grants with a priority score of approximately 140 or better, and a few with scores higher than 140 which are recommended by Council for "selective payment" at both the January and May Councils.

Question: Were you given any specific directive as far as when to reduce funding?

Answer: DHHS Secretary Heckler in testimony on March 5, 1985, before the Senate Appropriations Subcommittee, assured Senator Weicker that no multiyear awards would be made before July 1, 1985.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

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Answer: Several approaches are being explored in an effort to reduce administrative costs associated with awards. Examples include: reducing the size of continuation applications; delegating prior approval authority to grantee institutions for general purpose equipment (prior approval authority has recently been delegated for other categories); discontinuing council review of applications under an established dollar ceiling except for "special problems" (some institutes have already been granted authority to make awards under $50,000 without Council review); and acquiring appropriate personal computers for management, review, and technical staff to be used as an effective administrative tool. This network of computers could be a significant time-saving tool, thereby reducing current needs for overtime.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: Yes, there are several programs that have been developed to study and make recommendations for improved administrative efficiency at the NIAID. Some examples of this are: (1) a standing committee has been established, comprised of senior Institute staff, for the purpose of evaluating current and future Automated Data Processing requirements, and to identify ways to improve existing methods and to develop new methods of application for state-of-the-art computer technology, and thus reduce the time and personnel required for large volume data processing and manipulation projects; (2) the initiation of a comprehensive review and analysis of new methods and procedures for the preparation, compilation, and distribution of grant application packages which are required for review purposes; (3) the recent development of a plan that will establish a mechanism by which research animal care functions (which were previously performed, at some considerable cost, on overtime by permanent employees) will be contracted out to private industry, and whose implementation will represent significantly reduced costs to accomplish this additional workload; and finally, (4) the initiation of a comprehensive system of sharing the clerical support workload of the Institute.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: One such procedure, which was begun in 1985, is a comprehensive annual review of positions by the Director, NIAID. This review includes the presentation of all positions, details of the assigned function of each, impact statements on the relative quality and priority of the work performed by each, and overall staffing rationale for each organizational entity of the Institute. Despite its recent initiation, the annual review process has already proven to be a useful and effective management tool in the goal of maximizing staff utilization, by the identification of areas of workload flexibility thereby allowing for reassignment of available staff to the highest priority research projects. In addition, the Institute is in the final stages of developing a revised and comprehensive system for financial review and planning. This new system will consolidate financial reviews which were previously performed on a segmented basis, and will allow for more accurate and comprehensive alignment of research priorities across all the

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funding mechanisms available to the Institute. This process will reap considerable savings in senior staff time which was previously expended on separate and distinct financial and program reviews. It is expected that some phases of this new review process will be implemented during 1986, and that all phases of this system will be fully operational by the beginning of 1987.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: Indeed, we are always careful to ensure the equitable and complete review of research grant applications and contract proposals. Following each review cycle, the Director, Extramural Activities Program, conducts a thorough review of operations to ensure that the review process has been conducted at maximum cost efficiency and with no adverse effects on the quality of review. Some cost effective measures that have recently been used to decrease administrative costs while at the same time preserving the integrity of the review process include: increased use of expertise in the Institute while remaining within that number allowable under regulation and the use of outside mail reviews when there is limited expertise within a chartered review committee. When necessary, project site visits are made to ensure a complete and equitable review.

FUTURE DIRECTIONS

Question: In what areas do you foresee your Institute's research programs expanding over the next several years?

Answer: In general, I would anticipate that our Institute's research programs will proceed in much the same directions as they are currently. Areas that we may expand and emphasize include studies on disorders of the immune system; e.g., asthma, various allergic disorders, and the acquired immunodeficiency syndrome. The NIAID will also continue to emphasize and expand our program for the Accelerated Development of New Vaccines, giving particular attention to improved pertussis vaccines, the new generation of hepatitis vaccines, and vaccines for malaria, herpes, and AIDS.

The NIAID has assumed responsibility for research on diseases which are major causes of morbidity and mortality in developing countries. Much of this work involves parasitic infections and is done through our intramural Laboratory of Parasitic Diseases. We hope to make programs for prevention of vaccine-preventable diseases and child survival in developing countries an important focus in the future. Another major effort of the Institute will be directed toward the development of antiviral agents for a number of viral diseases, with particular emphasis on AIDS. The Institute is also heavily committed to research in sexually transmitted diseases (STD) and will continue and hopefully expand this effort to concentrate on understudied areas such as pelvic inflammatory disease and STD caused by chlamydia.

Question: How much flexibility do you have within your current organizational framework to emphasize one area over another?

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Answer: There is considerable flexibility for changing emphasis from one area to another particularly with regard to the Intramural Research Program and contract-supported applied research. Adequate funding in these areas allows for fairly rapid shifts of emphasis. Significant shifts of emphasis in our grant supported research, the major part of the NIAID budget, is less flexible. While it is possible to publicize NIAID's interest in particular areas through Program Announcements and Requests for Applications, the grants program is still primarily a product of the interests, ideas, and quality of research proposed by investigators in academia.

Question: Do you foresee any changes in the way research priorities are set?

Answer: At the present time, I do not foresee any real changes in the way research priorities are set. I think that it is important to have the flexibility that we have in intramural and contract-supported research so that we can respond quickly to important public health problems. I also feel that it is important to continue to support original ideas and research approaches generated by talented scientists in our Nation's academic institutions. Their original ideas and research provide the foundation for the applied research directed at solving specific public health problems.

NATIONAL ACADEMY OF SCIENCES (NAS)/INSTITUTE OF MEDICINE (IOM) REPORT REACTION

Question: The IOM study committee that was convened to review the organizational structure of NIH made a number of recommendations concerning research planning and functions at the individual Institute level, as well as NIH-wide (pp. 18-19; 24-29; 32-33; and 34-37). What is your reaction to the IOM committee's recommendation that "Institute directors should more uniformly involve their (National) advisory councils in broad program and policy issues"? (p. 35)

Answer: I endorse this recommendation. We have in the past involved the National Advisory Allergy and Infectious Diseases Council in broad program and policy issues, and we will continue to do so in the future.

Question: Would this change the way in which your Institute currently interacts with its advisory council?

Answer: This would not change the way in which our Institute currently interacts with our national advisory council.

Question: By what mechanism(s) does the NIAID National Advisory Council presently provide your Institute with program and policy advice?

Answer: At each Council meeting, the Council considers first in subcommittees, and then in full Council, all grant applications together with the designation of specific grants for "selective payment" and the suggested disposition of special problems with grant applications such as ethical concerns, biosafety

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considerations, rebuttal letters, proposed budget restoration, or foreign grants.

Proposed new NIAID programs are discussed with Council. For example, at the September 17-18, 1984 meeting, Council discussed and endorsed embarking upon the proposed NIAID Minority Research Enhancement Program.

Status reports are given to Council. For example, at the May 21-22, 1984, meeting, the NIAID Director reported on NIAID outreach activities, and the Director of the NIAID Microbiology and Infectious Diseases Program reported on the Institute's Accelerated Development of New Vaccines Program.

Special Council working groups are sometimes appointed. For example, at the January 26-27, 1984, meeting, the Council Study Group on Sexually Transmitted Diseases reported to the full Council. Following their report, the NIAID Council voted to approve a series of recommendations to NIAID relative to research on sexually transmitted diseases.

Question: Do you think the IOM recommendations would substantially change the way your extramural research program priorities are set?

Answer: I do not anticipate that this IOM recommendation will substantially change the way in which our extramural research program priorities are set, since we have in the past involved the National Advisory Allergy and Infectious Diseases Council in setting our extramural research program priorities, and we will continue to do so in the future.

NAS/IOM STUDY

Question: The IOM committee recommended that, "where appropriate, support functions of individual institutes and other components would be clustered to reduce unnecessary duplication and expense." (p. 5, 34-35) What is your reaction to this "clustering" concept?

Answer: While we continue to explore ways to reduce unnecessary duplication and expense, I agree with the report's analysis that the current system is designed to maximize the effectiveness of the individual institutes in carrying out their respective research programs. Thus, I would not recommend any major change to the current system. I also share the following concerns expressed by the NIH regarding clustering:

a) To effectively manage, the top echelon officials of an Institute must have control over the budget office, grants management office, planning and evaluation office, and personnel office.

b) Individual standards would be compromised by different requirements set by multiple supervisors.

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c) Program identification by support staff is critical in maintaining efficient and effective work output, as well as morale.

d) Conflicts in setting priorities would arise and interfere with smooth functioning of administrative support staff.

Question: Do you think it would be feasible for your Institute?

Answer: For the reasons detailed above, I do not favor the "clustering" concept for NIAID.

Question: Which other Institute(s) would you envision being compatible with NIAID's areas of coverage as far as grants and contracts management, budgeting, etc?

Answer: While we work closely with certain institutes in specific scientific areas such as AIDS, kidney transplantation, asthma, etc. and collaborate on or co-fund mutually beneficial research projects, our overall areas of emphasis and research thrusts are diverse such that I envision no other Institute at NIH with which it would be fruitful or effective for NIAID to cluster.

Question: Do you think the IOM recommendation to grant the NIH Director greater budgetary authority (specifically a one percent discretionary fund to seed selected areas of research) would have an impact on your Institute's programs? (p. 5, 32)

Answer: I would support the recommendation that a discretionary fund be available to the NIH Director as long as the fund is independent of the amount appropriated to the individual Institutes for their separate functions and in no way would reduce the level of support for the Institutes. I also agree with NIH's proposal that the fund should include resources for both emerging cross-cutting research opportunities and public health emergencies.

Given the above stipulations, and if the NIH Director were given this authority, I expect that this could have a positive impact on NIAID programs.

Question: Also in this regard, would the idea of giving the NIH Director "limited authority to transfer up to 0.5 percent of the NIH budget across institute lines in response to a public health emergency" increase your Institute's ability to respond to such an emergency if it involved infectious or immune system diseases (such as, for example, the acquired immunodeficiency syndrome/AIDS)?

Answer: This kind of flexibility would provide a useful device for meeting unexpected research needs such as public health emergencies.

Question: If such funds became available, would you be able to utilize them on short notice?

Answer: Yes, we would be able to responsibly utilize such funds on short notice.

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Question: Would they more likely be used to fund extramural or intramural research?

Answer: In an emergency situation, we are able to move most quickly intramurally. This was the case with AIDS. We are later able, as was the case with AIDS, to followup with an expanded extramural effort in the area.

RESEARCH MANAGEMENT AND SUPPORT

Question: Dr. Fauci, last year's justifications indicated you planned to spend $16,314,000 on research management and support in 1985 and the 1985 effects statement recently submitted to the Subcommittee includes an adjusted figure of $16,365,000. However, on page 381 of this year's justifications the figure shown for research management and support in 1985 is $14,949,000. What accounts for this discrepancy?

Answer: The adjusted 1985 appropriation allows $16,365,000 for Research Management and Support (RMS), an increase of $51,000 over the President's request of $16,314,000 and $501,000 less than the appropriation before adjustments. These adjustments reflect the proposed rescission and funds withheld from obligation.

The difference between the adjusted appropriation of $16,365,000 for RMS and $14,949,000 shown in the 1985 column of the 1986 President's request, a decrease of $1,416,000, is a comparative transfer to the National Cancer Institute for changes in the Central Services financing mechanisms and formulas.

Question: On page 382 of the justifications you indicate you will begin to implement a comprehensive state-of-the-art automated data processing (ADP) plan developed in 1985. When will this plan be fully in place, how much will it cost in total, and how much money will it save the Institute?

Answer: A contract entitled "Design and Development of NIAID ADP State-of-the-Art Plan" is expected to be awarded in 1985. While the duration of this project is expected to be 12 months, substantial initial recommendations are anticipated after the first 6 months of the project. The Institute intends to begin immediate implementation of selective parts of these initial recommendations. Approximately $150,000 has been allocated for the development of the Institute's ADP plan. One of the major end products of the plan will be to outline the future costs required to fully implement advanced ADP in this Institute. The anticipated amount of money saved will not be fully apparent until after the study is completed. However, we expect a significant impact will be made, and most particularly in the forms of: curtailing proliferation of redundant systems and data bases, reduction of independent programs and conflicting information policies and systems, and the increased integration of emerging technology with the Department's mission. In summary, while the exact monetary value of the savings cannot be assessed at this time, we would expect not only considerable savings to be accrued from operational and overall productivity improvements, but also from more efficient utilization of both professional and support manhours.

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Current Status of Vaccine Development

Haemophilus influenzae. The capsular polysaccharide of H. influenzae type b (Hib), a linear polymer repeating ribosyl-ribitol-phosphate (PRP) units, a T-cell independent antigen, is effective in children over 18-24 months of age, and an application is pending for licensure of a PRP vaccine for use in this age group. However, PRP does not induce protective antibodies in infants, the group at highest risk. A number of research groups (academic and industrial) are developing conjugated, T-cell dependent vaccines. One such product, developed by Connaught Laboratories, consisting of PRP con conjugated to diphtheria toxoid, has been shown to be non-reactogenic and immunogenic in infants below the age of six months. An efficacy trial, sponsored by the NIAID, is now under way in high-risk infants in Alaska. Protection data should be available by the fall of 1987. Other studies conducted during the year have examined the outer membrane proteins of Hib organisms as potential antigens and the outer membrane components of B. pertussis as a possible adjuvant for enhancing the immune response to PRP.

Group B Streptococci (GBS). Two contractors, using somewhat different purification methods, have developed four GBS polysaccharide candidate vaccines. GBS types III (the most important), II, Ia and Ib vaccines have been prepared and the chemical and physical structures characterized. Safety tests in normal volunteers have shown that no adverse reactions occur. The vaccines elicited high titer antibodies as revealed by in vitro tests. In vivo studies indicated that GBS type III serum antibody from the volunteers will protect neonatal rats against lethal challenge with type III GBS. A pilot study is under way to immunize 40 pregnant women during their third trimester with type III GBS polysaccharide vaccine. The purpose of the study is to determine the antibody class elicited in the immunized mothers and whether the level of placental antibody transferred is adequate to protect the high-risk neonate. Progress to date indicates that 50 percent of the immunized mothers respond to the vaccine and that all have delivered healthy babies. It is anticipated that all 40 women and their neonates will be followed closely for 6 months post-delivery. Additional studies are in progress to determine whether or not women whose infants develop invasive GBS disease have a general defect in their immune response to all bacterial antigens or are non-responsive to a specific structural antigen.

Gonorrhea. A major objective is the development of a vaccine to prevent pelvic inflammatory disease (PID) in women infected with the gonococcus. A contractor (Drs. Buchanan and Hook, University of Washington) isolated and characterized the principal outer membrane protein (P-1) of the gonococcal cell wall from strains known to cause 90-95 percent of PID infections in the U.S. The P-1 material was safe in volunteers, with only minimal reactogenicity. Good serum antibody responses were elicited, with higher titers resulting when aluminum hydroxide adjuvant was used. Functional assays showed the serum antibody to be bactericidal. A candidate P-1 gonococcal vaccine, based upon serotypes 5, 7, 8, and 9, should be effective in preventing gonococcal PID, but field trials to demonstrate efficacy will be difficult to design. A pilot study now under way in

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volunteers will determine if the P-1 material can elicit antibody at mucosal sites (oral, genital, anal) and if attachment of gonococci to mucosal epithelium will be inhibited. Male volunteers only will be challenged intra-urethrally with virulent, penicillin sensitive gonococci to determine the protective and attachment-inhibiting activity of the anti-P-1 antibody at the mucosal surface. Early results of the study show some promise, but with only small numbers vaccinated and challenged, it is too early to predict final outcomes.

Another investigator has immunized female volunteers with a heat-killed, whole-cell, non-piliated gonococcal preparation. Reactogenicity was minimal, and a 4- to 8-fold antibody level was elicited in the volunteers; the rise was limited to the IgG fraction only. The rise in vaginal IgG titer was even greater, with an average 32-fold increase. The IgG response was equal against different gonococcal strains; therefore, antibody was produced against an antigen shared by heterologous strains. Although the investigators do not plan to develop this crude material as a candidate vaccine, they hope to dissect out the protective antibody(s) and to isolate and characterize the responsible antigen. This may lead to an entirely different type of gonococcal candidate vaccine.

Other investigators (e.g., Schoolnik, Stanford University) are studying the proteins of gonococcal pili to determine the conserved and the variable domains of these purified proteins. The goal is to develop a candidate pilus protein vaccine that would protect against a broad array of the gonococcal strains commonly present in the U.S. The candidate pilus vaccine tested by the U.S. Army only protected against its homologous gonococcal strain. It is estimated that there are at least 55 major serotypes in the U.S. so that a broader-based pilus vaccine is required.

Respiratory Syncytial Virus (RSV). The genome of RSV has been cloned and sequenced, revealing a complex paramyxovirus. This observation is of great interest because it is now known that RSV has four surface glycoproteins. Within the next year or two it may be possible to determine the relative roles of antibody to these proteins in resistance to infection. In addition, it may be possible to determine the antigens and other immunologic factors responsible for the potentiation of natural disease seen in vaccinees who had received the earlier inactivated RSV vaccines. Attempts to develop RSV vaccines using purified antigenic determinants produced by chemical synthesis are also being pursued. It is hoped that in the next two or three years candidate RSV vaccines will be available for testing in humans.

Parainfluenza Viruses. The observation that antibody to the fusion protein is related to resistance to infection has prompted an attempt to develop a fusion protein vaccine for parainfluenza type 3. Purification of the fusion protein has been difficult to date, but studies indicate that such a vaccine can protect hamsters from challenge. The general applicability of this approach to parainfluenza and respiratory syncytial virus vaccines is currently an active area of investigation.

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Whooping Cough. Encouraging progress is being made in identifying the antigens necessary to confer immunity to whooping cough, progress essential to the development of an improved vaccine to replace the current vaccine consisting of heat-killed bacteria. Bordetella pertussis, the cause of whooping cough, produces a number of bacterial products that singly or collectively are responsible for the manifestations of disease. These factors include pertussis toxin (PT), also called lymphocytosis promoting factor (LPF), filamentous hemagglutinin (FHA), adenylate cyclase (AC), agglutinogens, and hemolysin. The acellular vaccine developed by the Japanese is said to contain predominantly PT and FHA.

A chimeric plasmid has been used to introduct a transposon (Tn 5) into B. pertussis to create a series of mutants deficient in the production of one or more of these factors. When tested for its ability to produce respiratory infections in infant mice (the mouse protection assay of vaccine potency employs an intracerebral challenge), a mutant deficient in the production of FHA was almost as virulent as the wild type. Mutants deficient in the production of all toxins, a PT-deficient mutant, and a double mutant deficient in both AC and hemolysin were severely impaired in their ability to cause disease. These results indicate that PT is a more important vaccine component than FHA, and suggest that AC and/or hemolysin may be desirable components as well. Subsequent steps will include the production of purified PT and other components, either by extraction from filtrates or by identifying and cloning the relevant genes, and detoxifying these components without destroying their immunogenicity. A number of investigators, including those in at least three commercial firms, are attempting to do so.

An acellular vaccine consisting of two major pertussis proteins has been widely used in Japan for the past three years. NIAID has taken two approaches toward the development of a new acellular vaccine for use in the U.S.. The Institute has offered the use of its Vaccine Evaluation Units for studies on the safety and immunogenicity of any candidate preparations developed by commercial manufacturers. One American manufacturer has obtained bulk acellular pertussis component from a Japanese manufacturer and combined it with standard diphtheria and tetanus toxoids. A clinical trial with this DTP vaccine is now in progress at two evaluation units using 4-6 year-olds, 18-month-, and 6-month-old children. When compared with standard U.S. whole cell vaccines, the pertussis component of the study vaccine appears to be less reactogenic while maintaining immunogenicity when given as a booster immunization. In addition, NIAID awarded a three-year contract in the fall of 1983 to the Michigan Department of Public Health to develop an improved acellular pertussis vaccine containing the two principal immunizing antigens found in the Japanese vaccine. The contractor has been successful in isolating and purifying the two protein components and is currently attempting to further characterize the antigens, detoxify the proteins, and determine their biological activity using in vivo and in vitro assays. Due to high vaccine acceptance and low disease rates in this country, efficacy trials to determine that the vaccine provides adequate protection cannot be done here. Formal discussions are now being carried out with investigators in Sweden about future efficacy trials in that country, with a possible start date of early 1986.

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Influenza. Clinical studies of the cold-adapted (ca) vaccines in adults and children have shown that these vaccines are safe and antigenic. Emphasis has now been directed at the clinical evaluation of these vaccines in high-risk patients, particularly the elderly and children with cystic fibrosis. The first studies in these two groups of patients were begun during the last year. Preliminary data indicate that the ca vaccines are safe and antigenic in elderly patients; confirmation and extension of these studies are needed. Six type A ca vaccines have now been tested with no evidence of genetic instability or transmissibility. These six vaccines were also found to be infectious and antigenic. They are superior to current inactivated vaccines in that they are able to induce an immune response that inhibits viral shedding and lessens the duration of shedding. Bivalent live, attenuated influenza A vaccines were successfully tested in adults and children; no evidence of viral interference was detected and the subjects responded to both antigens in the vacccine. Emphasis has now been placed on the development of an attenuated influenza B vaccine. Two possible donor viruses are currently being evaluated in the laboratory and in animal studies. Reassortant viruses made from these donor viruses are being generated, and it is anticipated that clinical studies in humans for safety and antigenicity will begin within the next six months. The development of attenuated influenza A vaccines using an attenuated avian virus as a donor has also progressed steadily during the last year. The avian virus has now been used to successfully attenuate three wild type, virulent viruses. Attenuated influenza vaccines derived from avian donor viruses appear to be similar to the ca virus in their antigenicity, safety and reactogenicity.

Cholera. The search for a better cholera vaccine has been stimulated by studies in volunteers demonstrating that natural infection is followed by solid, long-lasting immunity. The goal is to design safe oral vaccines, either killed or attenuated, that can provide 90-100 percent protection for several years after one dose, or after a closely spaced series of doses. Oral immunization, rather than parenteral immunization, is more likely to stimulate the protective intestinal immune response of secretory IgA antibodies, and live organisms are likely to stimulate a more effective mucosal memory response.

The oral vaccines currently under development are of two classes: inactivated V. cholerae strains combined with altered, non-reactogenic toxin or purified toxin subunits, and attenuated V. cholerae strains. Studies of inactivated vaccines have focused on products combining whole vibrios with either glutaraldehyde-treated toxin, heat-aggregated toxin (procholeragenoid) or the purified B-subunit pentamer of the toxin that binds to the intestine. In a small number of volunteers the protective efficacy of these vaccines was disappointing, ranging from 27 to 67%. WHO is sponsoring a field trial in Bangladesh of a combined oral B subunit plus killed whole cell vaccine.

The first live vaccine strain of V. cholerae to be tested in volunteers was prepared by nitrosoguanidine mutagenesis. This strain, Texas Star-SR, produced ample amounts of the non-toxic, antigenic B subunit portion of the toxin molecule, but only very small quantities of the toxic A subunit portion that activates secretion. Although

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Texas Star-SR colonized the small bowel and induced antitoxin or vibriocidal antibody responses in 85% of volunteers, it provided only 61% efficacy against diarrhea caused by V. cholerae challenge and caused mild diarrhea in 24% of vaccinees. Encouraged by these results, investigators attenuated pathogenic V. cholerae by specifically removing genes encoding the cholera enterotoxin, while preserving genes encoding all other antigens, such as lipopolysaccharide, outer membrane proteins and colonization factors likely to be involved in immunity. This method is free of the disadvantages of nitrosoguanidine mutagenesis, which involves the induction of uncontrolled and unwanted mutations and the theoretical risk of reversion to toxigenicity.

Two strains of V. cholerae with precise genetic lesions have been constructed by DNA recombinant techniques and tested in volunteers. The first strain, JBK 70, has no cholera toxin genes (A minus, B minus). In the second strain, CVD 101, its toxic A subunit gene was deleted while the immunogenic, but non-toxic, B subunit gene was retained and expressed (A minus, B plus). Of a small number of volunteers fed strain JBK 70, 90% were protected against severe illness. Some volunteers, however, developed low-grade diarrhea after vaccination, an occurrence which led to the discovery that strains JBK 70 and CVD 101 each produce a heat-labile toxin different from cholera toxin. The existence of this second toxin in V. cholerae was not previously known. Attempts are under way to characterize, clone and then remove the gene for this new toxin from these attenuated vaccines to render them truly avirulent and acceptable for use as live oral vaccines in American travelers. Phase 1 and phase 2 (field) trials of CVD 101 are being planned for Kenya in 1984-85.

Dysentery. Until now, oral killed or attenuated Shigella vaccine candidates have lacked necessary safety, stability or efficacy. Using genetic engineering, plasmid genes coding for the protective antigen on Shigella sonnei have been inserted into the genome of the Ty21a vaccine strain of Salmonella typhi (see below) by Army scientists. The resultant transconjugant strain (5076-Ic) manifested both S. sonnei and S. typhi antigens, was stable and protected mice against challenge with either S. sonnei or S. typhi. Doses were well tolerated and safe when fed to volunteers. The 5076-Ic vaccine strain afforded an efficacy rate of 48 percent against diarrhea following a challenge of volunteers with virulent S. sonnei, and protected the volunteers completely against fever. These volunteer studies are continuing.

A similar recombinant vaccine, consisting of a protective Shigella flexneri type 2A gene in a replicating, nonpathogenic, enteric E. coli host, awaits human trials. Based on this strategy, it may be possible to construct an "all purpose" oral, attenuated dysentery vaccine consisting of protective antigens of S. sonnei and S. flexneri, types 2 and 3, and S. dysenteriae type 1, each in avirulent E. coli host and then combined to give a multivalent preparation.

Rotaviruses. Several approaches to the production of a rotavirus vaccine are being pursued. One strategy used by NIAID investigators was to attenuate an otherwise virulent strain of human rotavirus by passing it repeatedly in gnotobiotic piglets and cell culture. This

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attenuated strain, called WA, represented the first oral rotavirus vaccine candidate. It was fed to volunteers, but when questions about its passage history arose, further trials were suspended.

Another strategy involves the use of an animal rotavirus strain that can infect man and evoke cross-protective immunity without inducing illness. In Finland an attenuated animal strain, RIT 4237, derived from the Nebraska calf diarrhea virus strain of bovine rotavirus, has been shown to be safe, immunogenic and efficacious in protecting infants against rotavirus diarrhea. One dose resulted in an 88 percent reduction of severe rotavirus diarrheal episodes. Field trials are under way to determine the duration of this protection, the extent of heterologous cross-protection against the four human rotavirus serotypes, optimum dose and schedule, heat stability, the effect of feeding on vaccine "take," and the extent it may interfere, if at all, with oral poliovirus immunization.

Another oral candidate vaccine strain derived from animals was isolated from a rhesus monkey with diarrhea. This rhesus rotavirus has been safe and immunogenic in adult volunteers; tests in children and infants are under way. If successful, the rhesus and bovine strain vaccines will be tested concurrently in field trials to be conducted in the U.S. and overseas under NIAID, USAID, and WHO sponsorship.

In yet a third strategem, fastidious human rotaviruses have been cultivated by mixing them with less fastidious animal rotavirus strains in tissue culture. In this system, designed to produce reassortant rotaviruses, the segmented genes of the non-cultivatable human rotavirus that restrict growth in vitro are replaced by the animal genes permitting such replication, while the genes coding for the antigenic coat of the human strain are preserved. The resulting progeny viruses not only grow efficiently in cell culture, but also have the neutralizing specificity of the human rotavirus parents. Reassortants have been developed at NIAID using wild-type bovine or rhesus rotavirus and each of the four human rotavirus serotypes. They have not yet been tested in man.

The recent availability of both cloned rotavirus genes and the protein sequences of important rotavirus antigens should permit yet additional approaches to vaccine development. For example, cloned rotavirus genes have been incorporated into a prokaryotic expression vector in E. coli K-12. If the synthesis of rotavirus antigens can be achieved in such systems, a large amount of antigen could be produced for subunit vaccines and for the structural analysis necessary for construction of a synthetic vaccine. The degree of cross-protection between serotypes and the duration of that protection are particularly critical questions, because it is not yet known whether all four serotypes must be included in a vaccine.

Typhoid. The development in Switzerland and the recent successful field trial in Egypt of a live, oral S. typhi vaccine represents a major advance. This vaccine consists of a mutagenized, enzyme deficient strain of S. typhi (Ty21a) that is incapable of utilizing galactose after this sugar enters the bacterium. Ty21a successfully proliferates in sufficient numbers to immunize the bowel, before the galactose accumulates in the cell and kills it. In Chile, ongoing

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field trials of Ty21a, using a more practical vaccine formulation and dosage schedule than used in Egyptian studies, has shown an efficacy rate of 75 percent, somewhat less than the three-year, 95 percent efficacy rate reported in Egypt. Both trials provide nearly perfect vaccine safety records.

Hepatitis A. Both Dr. Robert Purcell, of NIAID's Intramural Program, and Merck, Sharp and Dohme are working on a live vaccine for hepatitis A virus (HAV). Dr. Purcell passaged HAV in tissue culture cells to attenuate the virus, and then serially cloned it to produce a "master seed." The 20th passage was partially attenuated for chimpanzees but not for marmosets--two species that can be infected with HAV. A 30th passage is now ready for evaluation.

Multiple approaches are being employed in the development of an inactivated vaccine. The Army plans to test a heat-killed whole virus vaccine. Recombinant DNA copies have been made covering more than 99 percent of the HAV genome. Two-thirds has been sequenced, including the major viral surface antigens. Expression of these surface antigens through recombinant DNA techniques is being done by NIAID in collaboration with Chiron Corporation. Synthetic peptides corresponding to portions of major surface antigens have been made in collaboration with Dr. Richard Lerner at Scripps and are being tested. Merck also has cloned and sequenced portions of HAV.

Hepatitis B. The major protein and antigen found on the surface of the hepatitis B virus (HBV) particle derived from plasma is called the surface (S) antigen (HBsAg). Also present in smaller quantities is a larger protein consisting of all of the amino acids of the S antigen plus an additional 55 amino acids coded by the pre-S region of the HBV genome. The pre-S protein binds to polymerized serum albumin and may be responsible for entry of HBV into liver cells. The presence of the pre-S protein is one difference between the NIAID and Merck HBV plasma-derived vaccines. The former contains particles with the larger (pre-S plus S) protein present, while the pre-S protein has been enzymatically removed from the latter during vaccine purification steps. The role of pre-S protein in the immune response remains to be determined.

Recombinant DNA (rDNA) techniques are being used to produce HBV vaccines in yeast cells (AmGen, Biogen and Merck) and in Chinese hamster ovary cells (Genentech). Merck has performed 1 clinical trials with volunteers; NIAID began Phase 1 clinical trials of the Genentech vaccine in 1984, and expects to do the same in 1985 for AmGen. Burroughs-Wellcome is conducting Phase 1 trials of the Biogen product. All of these rDNA vaccines presently consist only of S antigens.

The gene coding for the S antigen has been incorporated into vaccinia virus by Dr. Bernard Moss of NIAID. The hybrid virus induced antibody to HBsAg in vaccinated rabbits and protected chimpanzees challenged with live virus against disease.

Drs. Purcell, Gerin, and Lerner are utilizing synthetic peptides specified by the S and pre-S regions to identify the neutralizing and protective epitopes of HBV. Since peptides can be synthesized

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inexpensively, their use as vaccines may further reduce the cost of HBV immunization, provided an adjuvant suitable for human use can be developed.

Through an NIAID contract, the woodchuck has now been established as an animal model for two severe complications of HBV infection seen in the human population--chronic active hepatitis and primary hepatocellular carcinoma. The 1-2 year time span for the development of these sequelae in the woodchuck versus 30 years in man makes the woodchuck a superb model for quickly evaluating HBV vaccines and other therapeutic agents.

Chickenpox. Varicella, a highly contagious viral disease of children, is not usually associated with mortality or serious sequelae. However, it is a very serious problem in immunosuppressed children such as those with acute leukemia on chemotherapy. The NIAID has evaluated an attenuated varicella-zoster vaccine in leukemic children, and the results demonstrate that the vaccine is safe and immunogenic. Initial analysis suggests that the vaccine is effective in protecting these children from clinically significant chickenpox. There are numerous questions remaining about duration and nature of immunity, vaccine virus latency and zoster development, and these are being actively pursued. During FY 85, other children at high risk, (i.e., patients with Wilms' tumor or rhabdomyosarcoma) will be entered into carefully designed clinical trials with the attenuated vaccine. The manufacturer (Merck) has shown the vaccine to be safe and effective in normal children.

Genital Herpes. An efficacious, safe vaccine for genital herpes has yet to be developed and fully tested in humans. A subunit vaccine developed with NIH support and produced by Merck has been tested for efficacy in preventing recurrent disease and has had preliminary trials for preventing transmission between sexual partners. The results to date indicate failure in preventing recurrence and limited success in preventing transmission. Although the vaccine prevented development of lesions, it did not completely protect against transmission. Some vaccine failures resulted in subclinical infections that apparently became latent and then recrudesced with clinically manifest lesions. Lederle is collaborating with Molecular Genetics, Inc., to produce a vaccine using recombinant DNA (rDNA) technology. Human trials with this rDNA vaccine have not been reported.

Another approach to vaccine development has utilized rDNA technology to incorporate the viral gene coding for protective glycoproteins into vaccinia virus and then to immunize with the modified hybrid vaccinia virus. Tests in animals by Dr. Bernard Moss (NIAID) have shown this approach to be feasible, but no human trials have been initiated to date. These rDNA and subunit vaccines may be missing an important component of the virus responsible for or controlling the development of latency. Investigators in Seattle have found that antibodies to a viral protein, identified as p66, are associated with the immune response to natural infection, whereas no antibodies to p66 were detected in individuals who were immunized with subunit vaccines containing only viral glycoproteins. This p66 protein may serve as a useful marker to distinguish individuals immunized only with the rDNA or subunit vaccines from those which were naturally

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infected. The role of p66 in the immune response is being investigated.

The development of a live herpes virus vaccines by Dr. Bernard Roizman (University of Chicago) is progressing. Success in deleting both the latency potential and neurovirulence from a candidate for a live vaccine has been demonstrated in animals but not tested in humans. Two prototype live vaccines are being produced for additional testing in animals and possible trials in humans.

Malaria. Development of a vaccine for malaria is rapidly progressing in three different areas. The most advanced is the antisporozoite vaccine. Antigens isolated from the surface of sporozoites of the rodent malaria, P. berghei, the primate malarias, P. knowlesi and P. cynomolgi, and more recently, the human malaria, P. falciparum, have been shown to stimulate formation of antibody that abolishes infectivity of sporozoites. A recurrent immunodominant epitope of the circumsporozoite (CS) protein of P. knowlesi has been identified and its amino acid sequence determined. This peptide has been coupled to protein carriers and injected, with complete Freund's adjuvant, into rodents and monkeys which later developed antipeptide antibodies. Similarly, a species specific immunodominant region with repetitive epitopes has been identified in P. falciparum and P. vivax CS proteins. Although genetic variations in the protein were observed, the immunodominant region was invariant, indicating its potential as a target for the immune response. Through screening of a genomic DNA library with a number of sera, two antigen-expressing clones have been found and their DNA sequenced. One antigen is found on schizonts and infected RBC membranes, and the other is present in all stages of the parasite. Hybrid proteins from these antigens have been purified and are presently being tested against P. falciparum in monkeys. Workers at the NIH and their collaborators have cloned the gene for the CS protein of P. falciparum. This gene encodes a protein of 412 amino acids with 42 tandem repeats of a tetrapeptide. Monoclonal antibodies against the immunodominant portion of the CS protein were inhibited from binding to the protein by synthetic peptides of the repeat sequence. Two regions of homology exist between the CS protein of P. falciparum and that of P. knowlesi. Conservation of the regions in parasites widely separated in evolution suggests a function such as binding to liver cells and indicates a possible invariant target for the immune system.

The second approach to a malaria vaccine is directed toward the asexual stage. Recently an antigen of P. falciparum has been identified on the surface of infected RBCs and is thought to be transferred there following invasion by the parasite. Infected RBCs treated with sera from immune donors bind antibody which, when eluted, recognizes a major and two minor parasite polypeptides. Screening of a genomic library with human antibodies eluted from infected RBCs has resulted in isolation of several clones that produce polypeptides reactive with those antibodies. Immunogenic characterization of these polypeptides is in progress. Stage specific P. falciparum genes that are expressed late in schizogony have been recently identified. These merozoite-schizont-specific cDNAs can be expressed in large quantities. Such bacteria-produced polypeptides correspond to specific merozoite proteins. DNA sequence analysis has allowed production of peptides that cause the generation of specific antibody. Large

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quantities of such merozoite antigen or synthetic peptides are now available for protective studies in animals.

The third approach to vaccination involves blocking transmission from the mosquito to man. This may be accomplished by blocking infectivity of the parasite to the mosquito, blocking fertilization, or blocking development of the ookinete. Monoclonal antibodies that block fertilization or development of ookinetes have been used to identify related proteins in gametocytes and zygotes of P. falciparum. Transmission blocking immunity, while not directly protecting an immunized individual, would interfere with transmission of malaria within the community.

Finally, genes coding for one, or conceivably all, of the stage-specific antigens could be incorporated into a hybrid vaccinia virus.

Acquired Immunodeficiency Syndrome (AIDS). This devastating disease had just been recognized when NIAID developed its vaccine priority list. Now, the identification of the retrovirus HTLV-III/LAV as an essential factor in the etiology of AIDS makes possible attempts to develop a vaccine. Large-scale production of the virus will allow characterization of its antigens, immunogenic properties, and envelope proteins. Numerous approaches will be explored by NIAID, NCI, and private firms to develop a safe and effective HTLV-III vaccine. These approaches include: (1) a subunit vaccine from cultured virus, (2) a recombinant DNA vaccine, (3) an infectious recombinant vaccine (e.g., hybrid vaccinia), (4) an anti-idiotype vaccine, and (5) a synthetic peptide vaccine. The variation among the different isolates of the HTLV-III virus suggest that a polyvalent vaccine may be needed.

Group A Streptocci. Rheumatic valvular disease and acute glomerular nephritis are the most serious sequelae of Group A streptococcal (GRAS) infection in children. These diseases have been largely controlled in the U.S., owing to widely available antibiotic therapy, and are no longer the end result of common "strep sore throat." In underdeveloped countries, however, these sequelae remain a major health problem. Several groups of investigators are attempting to develop an effective vaccine to protect children from these sequelae. One investigator (Beachey, University of Tennessee) has prepared synthetic peptides covalently linked to polylysine; these were highly immunogenic in rabbits and induced no heart tissue cross-reactivity. The synthetic sub-peptide region of the GRAS type 24 M protein was also conjugated to tetanus toxoid; this showed great immunogenic activity in eliciting type 24 M antibodies in rabbits. The smallest peptide, of only 13 M protein residues, was as immunogenic as the longer peptides. No reactions were seen against human heart tissues in passively protected mice. Thus, chemically synthesized peptide fragments of as few as 13 residues of streptococcal M protein can elicit protective anti-streptococcal antibodies without evoking heart cross-reactive antibodies. It is expected that this material will be tested in limited clinical trials within a year.

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Leprosy. NIAID has no candidate Mycobacterium leprae vaccine at present. A number of M. leprae specific antigens have been identified and purified by Institute-supported investigators; specific antigen(s) with vaccine potential may soon be found.

The World Health Organization (WHO) is presently funding the testing of two M. leprae vaccines. A vaccine composed of heat-killed M. leprae and live BCG bacteria is being tested in Venezuela by Dr. Jacinto Convit. The second vaccine is composed of heat-killed M. leprae cells only. It is presently being tested in the U.S. for adverse reactions, dosage level and activity (skin test reaction) under the supervision of Dr. John Trautman, National Hansen's Disease Center, Carville, Louisiana, and Dr. Ward Bullock, University of Cincinnati School of Medicine, Cincinnati, Ohio. When these preliminary tests are completed, a trial of the vaccine will be carried out in India. It will be a number of years before the effectiveness of these vaccines can be determined.

Pseudomonas. Development of candidate vaccines for burn/trauma patients and for cystic fibrosis (CF) patients is being pursued by several investigators. The candidate vaccines are of different antigenic determinants from different pseudomonas strains. A vaccine for CF patients would most likely be based on the muco exopolysaccharide, though this material requires further study and development prior to clinical trials. For burn/trauma patients a purified high M.W. polysaccharide is the most promising vaccine material, and such a vaccine should soon be ready for Phase 1 trials. This high M.W. polysaccharide product represents an immunogenic and non-toxic form of the lipopolysaccharide O side chain and is 95-100 percent pure carbohydrate. It provides serotype specific immunity; there are seven serotypes of P. aeruginosa now recognized, called the Fischer serotypes. Thus, a polyvalent vaccine would contain polysaccharides from seven serotypes. Such a high molecular weight polysaccharide candidate vaccine has induced a good immune response in animals. Because burn or trauma patients may not mount a good immune response in time, the most likely approach would be passive immune therapy, using high titered polyvalent immune serum globulin obtained from vaccinated normal volunteers.

A purified mucoid exopolysaccharide Pseudomonas material is under development for its potential use as a vaccine to immunize CF patients. This could be accomplished by immunizing the patients in their early childhood years (less than 4), prior to colonization by the pseudomonas organisms. Again, this candidate vaccine would most likely be a polyvalent product composed of the seven Fischer serotypes. Investigations are proceeding along these lines, with the expectation that initial human studies may be considered within a year or two.

Cytomegalovirus. Attempts to develop a vaccine against human cytomegalovirus (HCMV) have been limited largely to the attenuated live Towne strain vaccine which has been shown to ameliorate the disease associated with HCMV in transplant recipients. The vaccine does not prevent infection with virulent HCMV but appears to limit infection and reduce symptoms. Because HCMV infections are major clinical problems in immunocompromised patients, the use of the vaccine has

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been applied mainly in antibody negative transplant patients, particularly renal transplants, where its greatest efficacy has been noted. The development of genetically engineered HCMV vaccines is being considered, but substantially more knowledge of the biology and pathogenesis of HCMV must be gained to make such an approach feasible.

Dengue. The U.S. Army has been pursuing development of an effective vaccine against dengue for a score of years. Initial efforts were directed toward developing live virus vaccines attenuated by passage in mice, in tissue culture and even in humans. Only with the dengue 2 serotype has this met with any success to date, and even this candidate vaccine suffers from overattenuation. With the advent of recombinant DNA, new approaches to immunization against dengue are being explored by both the NIAID and the Army. The strategy is to isolate the virion RNA of dengue, prepare complementary DNA by reverse transcription, map the genes for surface glycoproteins, and insert the genes into cloning vectors. From here the strategy diverges to (1) expression of the genes for envelope glycoproteins to produce subunit vaccines, and (2) insertion of the genes into vaccinia virus for use as a live vaccine. To date, the state of the science is still at the stage of isolating the virion RNA and preparing full length cDNA for sequencing and genetic mapping. Safe, efficacious dengue vaccines are probably a decade away at the current rate of progress.

Rabies. Several types of rabies vaccines have been developed since Pasteur's original desiccated brain vaccine. The most notable recent vaccine is the one produced from virus grown in human diploid cell cultures (HDRV). This killed virus vaccine is highly efficacious both as a pre-exposure prophylaxis and as a post-exposure treatment (with immune gamma globulin). The purity and potency of the HDRV have eliminated the discomfort and dangers of the earlier vaccines and reduced the number of doses from 23 to 4 or 5. HDRV has also overcome the low potency and immunogenicity shortcomings of the previous killed duck embryo vaccine. However, the expense of the HDRV has precluded its full utilization in many developing nations. Although the use of a continuous cell line (e.g., Vero) should reduce cost, development of better and less expensive vaccines is still being pursued. The viral genome of rabies has been isolated, cloned as complementary DNA, sequenced, and mapped for genes encoding the surface glycoproteins (gp). The gp gene has been inserted into vectors for cloning and expression in bacteria. Unfortunately, the expressed proteins appear to be toxic to the bacteria and other expression systems are sought. The gp gene has been inserted into vaccinia virus and the modified vaccinia immunizes animals against rabies. This type of vaccine has tremendous potential for developing countries of Central and South America and Asia where rabies is endemic and a serious problem. The modified vaccinia virus vaccine has the potential for immunizing animals by ingestion. Thus, a safe vaccine for feral and domestic animals is not only possible but may prove very practical. Such improved vaccines could reopen Central America to dairy and beef cattle where, at present, bat rabies makes such ventures economically impractical.

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Leishmaniasis. Human trials, using a live promastigote vaccine for cutaneous leishmaniasis, have been reported but further study has been deferred because of undesirable side effects. Studies using more refined antigens from promastigotes are in progress.

Toxoplasmosis. A method has recently been patented in which animals and man can be immunized against Toxoplasma gondii, the causative agent of toxoplasmosis. The basis of the method is the utilization of a mutant strain of T. gondii which is of low virulence and persists in the vaccinated host for only a short time. This vaccine can be used in both man and animals and is intended for immunization of high risk patients such as women contemplating pregnancy. Another patent has been granted for a method of immunizing cats to prevent oocyst shedding. The oocyst is the form infective for humans. Live organisms, in the form of cysts, are fed to the cat and subsequent treatment with an antitoxoplasma drug prevents the parasite from completing its life cycle, which terminates in oocyst production. However, the initial exposure to the parasite is sufficient to induce immunity to subsequent challenge.

Schistosomiasis. Various approaches to immunization against human schistosomiasis have been tried. While complete protection has not been achieved, successful immunization using irradiated larval schistosomes has been reported. Recently, a new immunization technique has been described in which lysed invasive larvae or soluble worm extract administered with the bacterial adjuvant, BCG, reduced the intensity of a challenge infection up to 70 percent. Such intensity reduction would greatly reduce the degree of disease. Of especial interest is that the soluble antigens from adult worms produced significant immunity, indicating that membrane reactivity may not be as important as once thought in resistance to challenge infections in the mouse model.

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NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

STATEMENT OF DR. RUTH L. KIRSCHSTEIN, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

WILLIAM T. FITZSIMMONS, EXECUTIVE OFFICER, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. Next we welcome Dr. Ruth Kirschstein, Director of the National Institute of General Medical Sciences. This Institute supports research and training in the basic biomedical sciences. It is basic research that has led to our greatest understanding of biology and represents the indispensable foundation for all targeted clinical research.

Dr. Kirschstein is here to defend her request for a fiscal year 1986 budget that is $24 million less than the $482 million appropriated in fiscal year 1985. However, by borrowing from the fiscal year 1985 budget, the Institute is able to claim a 4 percent increase in budget authority for fiscal year 1986.

Dr. Kirschstein, before you proceed we will insert your statement in the record.

[The statement follows:]

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Statement of Dr. Ruth L. Kirschstein

I am honored to have presented to you the programs of the National Institute of General Medical Sciences (NIGMS) for the past 10 years, and to be here before you again for the eleventh time. This Institute supports studies that are not targeted to any specific disease or population group, but are crucial to furthering our knowledge about life processes. Such research forms the basis for the more disease-oriented investigations supported by other components of the National Institutes of Health.

Mr. Chairman, these are very exciting times in the field of biomedical research. I am proud to say that much of this excitement is the result of the knowledge that has been obtained thanks to the concepts, tools, and technologies developed by NIGMS grantees, and, as a result, the increasing opportunities to solve many remaining biomedical problems. Three of our grantees were among the 19 scientists recently awarded the National Medal of Science for their research: Dr. Paul Berg of Stanford, for his contributions to an understanding of gene expression; Dr. Roald Hoffmann of Cornell, for his creative application of theories to organic and inorganic chemistry; and Dr. Richard Zare, also of Stanford, for his seminal contributions to molecular spectroscopy, photochemistry, and chemical reaction dynamics. These scientists and others, also supported by NIGMS, are expanding the horizons of biomedical research and contributing to the applications of research results.

Biotechnology

Nowhere is this more evident than in the fast-growing field of biotechnology. NIGMS has played an important role in supporting the studies that underlie many of the technological advances that are benefiting both human health and the Nation's economy. Investments in basic research made 10 or more years ago are now coming to fruition. For example, recombinant DNA technology, developed over the past decade, largely with NIGMS support, is now being used over a wide range of industries to improve agricultural production and, by drug companies, to produce new products as well as to dramatically increase the quantity, efficacy, and purity of therapeutic and diagnostic agents. Now but similar studies being done now will help the United States maintain its scientific leadership into the twenty-first century.

Nuclear Magnetic Resonance (NMR)

Today, a variety of new technologies are being developed and refined. One of the most exciting and versatile is nuclear magnetic resonance (NMR) spectroscopy. NIGMS has supported research in the development of this originally rather exotic technology for many years and has watched it become an extraordinarily powerful tool affecting progress in virtually all areas of biology and medicine. NMR is being used to examine the detailed structure and changes in two-dimensional and three-dimensional configurations of proteins (the body's building blocks) and nucleic acids (the genetic material) in relation to their functions. Techniques such as NMR are used synergistically with the tools of modern genetics to develop new chemical theories regarding molecular activity. The genetic tools provide the precisely modified proteins, and the spectroscopic tools, such as NMR, identify the structural properties of these proteins. The proposed

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theories, together with the use of computer visualization, help in the interpretation of how modification in structure can lead to change in function. The development of new models can then be tested by experimentation. An example of a protein which has been modified and studied in this way is beta-lactamase, an enzyme which is responsible for infectious bacteria developing resistance to penicillin therapy. In another application of NMR, the transformation of nutrients and other chemicals can be followed within living tissues--at present, the best way to perform such studies.

At the same time, further refining of the instrumentation has led to the development of NMR for diagnostic imaging (similar to X-ray techniques). NIGMS grantee Dr. Paul Lauterbur of the State University of New York, Stony Brook, received the Lasker Award in 1984 for this outstanding work.

Genetics

Using other tools, such as recombinant DNA techniques, NIGMS grantees are providing further details of chromosome and gene structure. Scientists have also explored how such structure accounts for the function of genes as a blueprint for the human body--a blueprint, moreover, that is present in all the cells that make up the body. However, a major problem for biomedical researchers still exists: How are certain parts of the blueprint selected to act in a particular cell at a specific time while other parts lie dormant? This is one of the central questions in human development and is obviously of great relevance to an understanding of abnormal development. Furthermore, the switching on or off of particular genes is a feature of many genetic diseases, and may also play a role in diseases not traditionally considered to be hereditary; for instance, certain viral infections and cancer.

While it has been recognized for many years that all the genes present in a cell are not active, nevertheless the genetic material has been thought to be basically stable. That this general picture of stability is correct is, of course, supported by common experience. Horses beget horses, flies remain flies. But there is more turmoil beneath the genetic surface than one might think. As a result of much work by NIGMS grantees, it is becoming clear that certain segments of DNA (the basic genetic material) move around and are inserted in new places on the same chromosome, or even on a different chromosome, and that at least some of these moves are purposeful and serve to benefit the organism. Furthermore, it has been known for some time that stretches of DNA which have suffered traumatic "hits" by radiation or toxic chemicals can be repaired by special enzymes available in the vicinity of the chromosomes. These two facts give rise to a new concept of the gene as a dynamic entity normally subject to a variety of influences and changes. This means, on the one hand, that it has turned out to be much more difficult than anticipated to understand how genes function; but, on the other, it adds a new dimension and perspective to the key biologic phenomenon of adaptability. How the body continues to function in the face of environmental stresses of all kinds is an important question in medicine, and an understanding of this phenomenon at the molecular level is essential to finding ways to assist us in overcoming such stresses. For example, the specialized cells of the body that produce increased amounts of antibodies, when exposed to foreign substances, do so by activating specific parts of the genetic apparatus. How this speci-

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ficity is possible, and how the overall immune process is regulated, are major challenges to Institute grantees, and of great ultimate relevance to the management of many human diseases--among them immune disorders and infections.

Gene Mapping

Among the genetic diseases for which progress has been made is, of course, Huntington's disease. Last year we told you of the remarkable discovery of a genetic marker which appears to be associated with the gene for this disease. As was done in studies of Huntington's disease, the techniques of "gene mapping" and "chromosome walking," developed by NIGMS grantees, attempt to localize a presumably defective gene in the absence of any cellular or molecular information such as identification of a corresponding defective protein product. By studying specific overlapping fragments of DNA, scientists can "walk" along the chromosome to bracket a smaller and smaller area in which the gene of interest may be present. Recently, a new method of separation of DNA fragments has been developed. It uses electrical fields to separate larger DNA fragments than was previously possible. This enabled geneticists to take larger "steps" as they "walk" along the chromosome in order to painstakingly pinpoint the location of the gene. These techniques are now being used to try to identify markers associated with, or the genes responsible for, the many genetic disorders about which we know little except that they cause devastating illness and disability. Diseases such as cystic fibrosis, muscular dystrophy, and neurofibromatosis are now being studied by grantees of other Institutes using not only the techniques of gene mapping developed by NIGMS grantees, but also cells obtained from patients with these diseases. These cells are grown in culture, stored, and distributed by the NIGMS-supported cell bank in Camden, New Jersey.

Cell Membranes

As we learn more and more about genes, we must also add to our knowledge of the cell, which is the fundamental unit of all living organisms. The cell contains a number of minute structures called organelles and is surrounded by a wall or an outer cell membrane. The body's most characteristic constituents, proteins, are manufactured inside the cell under the control of genes. Many of these proteins, such as enzymes, must leave a particular cell in order to perform their vital functions in other parts of the body. The outer cell membrane constitutes a barrier to the movement of proteins, and NIGMS grantees have discovered much about how that barrier can be crossed and about the energy needed to transport proteins, such as hormones like insulin, to the locations where they are needed.

We know, too, as a result of work by NIGMS grantees, that the outer membranes of certain cells have specialized areas called receptors, which recognize and bind to specific molecules outside the cell--molecules such as enzymes, hormones, or drugs. It is only after recognition and binding have occurred on specific sites of the cell membrane that the desired response--for example, to a drug--can be triggered. NIGMS is supporting much work on enhancing this recognition so that drugs can act more effectively to overcome disease.

Furthermore, scientists are learning how to specifically design or tailor a chemical so it can be recognized by and bound to a cell

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with greater efficiency and specificity, thus preventing unwanted toxicities. It is in the production and design of these important chemicals that the field of biotechnology, mentioned earlier, has been most important. Compounds which are essential for a variety of purposes, such as drugs, growth factors, and certain hormones, and which have, up to now, only been synthesized in small quantities in nature, can be produced efficiently using methods which combine classical chemistry with newer recombinant DNA and hybridoma technology, as well as computer graphics by which the structures of molecules can be visualized as never before. These technologies are also being applied to the commercial production of fertilizers and solvents--important American industrial products.

The rapidity of advances in our knowledge of the incredibly complex microscopic world of our cells and our genes is almost overwhelming. However, it is clear that an understanding of how a cell membrane receptor interacts with an enzyme or of why a single minute change in one site on a gene alters its activity is the key to understanding most diseases and developmental abnormalities. The challenges associated with exploring these puzzles drive scientists to develop new technologies which not only aid their own studies but have important uses in other areas of investigation in biology and medicine and for industry, as well.

Research Training

What has made these enormous advances possible has been the creativity of biomedical research scientists, a creativity which is enhanced by the excellence of the research training they have received. A recent publication of the Institute of Medicine-National Academy of Sciences has clearly indicated that scientists who received support for their predoctoral research training by NIH fare better in their research endeavors than do others not so supported, and those supported by NIGMS do even better.

The National Research Service Awards (training grants) made by NIGMS sustain this excellence in the training of future generations of biomedical scientists who will explore new ideas and add to our knowledge. Two special research training activities supported by NIGMS are focused on areas of special need. The Medical Scientist Training Program (MSTP) is designed to increase the number of scientists who are both medical doctors and trained researchers and who can bring basic research into the clinical setting. The Minority Access to Research Careers (MARC) Program is designed to increase the numbers of minority scientists and has had a substantial effect on improving the science curricula at minority institutions.

We are only beginning to understand the mechanisms of life processes, despite the excitement of recent progress as I have outlined it. The basic, untargeted studies supported by NIGMS performed by well-trained researchers can be expected to fill in the important missing pieces of the many remaining puzzles regarding human health and disease.

Mr. Chairman, the 1986 budget request for this Institute is $458,484,000, a decrease of $24,122,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required

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adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985 this Institute will fund 776 new and competing grants, of which 93 will receive 3 years of support.

I will be happy to answer any questions.

Biography of Dr. Ruth L. Kirschstein

October 12, 1926. Brooklyn, New York

Education: A.B., magna cum laude, Long Island University, 1947. M.D. Tulane University School of Medicine, 1951.

Professional History: 1951-52, Internship, Medicine and Surgery, Kings County Hospital, Brooklyn, N.Y. 1952, Assistant Resident, Pathology, Veterans Administration Hospital, Chamblee, Ga. 1952-54, Resident, Pathology, Providence Hospital, Detroit, Mich. 1954-55, Trainee of National Heart Institute and Instructor in Pathology, Tulane University School of Medicine. 1956-57, Medical Officer, Resident in Pathology, Clinical Pathology, Clinical Center, NIH. 1957, Medical Specialty Board Certification, Pathology (anatomic and clinical pathology). 1957-60, Medical Officer, Pathologist, Laboratory of Viral Products, DBS, NIH. 1960-62, Chief, Section of Pathology, Laboratory of Viral Immunology, DBS, NIH. 1962-64, Assistant Chief, Laboratory of Viral Immunology and Chief, Section of Pathology, DBS, NIH. 1964-65, Acting Chief, Laboratory of Pathology, DBS, NIH. 1965-72, Chief, Laboratory of Pathology, DBS, NIH. 1971-72, Assistant Director, Division of Biologics Standards, NIH. 1972-73, Acting Deputy Director, Bureau of Biologics, FDA. 1973-74, Deputy Associate Commissioner for Science, FDA. 1974-present, Director, National Institute of General Medical Sciences, NIH.

Professional Organizations: American Association of Immunologists; American Association of Pathologists; American Society for Microbiology; Institute of Medicine, National Academy of Sciences.

Committee Memberships: Invited member of World Health Organization Expert Group on International Requirements for Biological Substances; Geneva, Switzerland, 1965 and 1971. Invited consultant to World Health Organization concerning problems related to the use of Poliovirus Vaccine, Live, Oral; Geneva, Switzerland, 1967. Member, Primate Research Centers Advisory Committee, Division of Research Resources, NIH, 1971-1975. Member, National Commission on Diabetes, 1975. Member, National Commission on Arthritis and Related Musculoskeletal Diseases, 1975. Chairperson, NIH Grants Peer Review Study Team, 1975-1976. Chairperson, PHS Genetics Coordinating Committee, 1976-1979. Member, Fogarty International Center Scholars-in-Residence Advisory Committee, 1977-1982. Member, NIH Coordinating Committee on Manpower, 1978-1983. Chairperson, PHS Task Force on Women's Health Issues, 1983-1984. Chairperson, PHS Coordinating Committee on Women's Health Issues, 1984present. Member, NIH Advisory Committee for the IOM Study of the Organizational Structure of the NIH, 1983-present.

Honors, Awards: Elected to Institute of Medicine, National Academy of Sciences, 1982. Doctor of Science, Honoris Causa, The Mount Sinai School of Medicine, 1984. DHEW Superior Service Award, 1971. PHS Superior Service Award, 1978. Presidential Meritorious Executive Rank Award, 1980. PHS Equal Opportunity Achievement Award, 1983.

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VALUE OF BASIC RESEARCH

Dr. KIRSCHSTEIN. Thank you, Mr. Chairman. I am pleased to be here.

The National Institute of General Medical Sciences supports, as you said, studies that are not targeted to any specific disease or population group, but that are, nevertheless, crucial to furthering our knowledge of life processes. Such research forms the basis for the more disease-oriented investigations supported by other components of the National Institutes of Health.

These are very exciting times in the many fields of biomedical research, and nowhere is this excitement more evident than in the fast growing field of biotechnology. You have heard from all of my colleagues from the other institutes about how biotechnology, particularly genetic engineering and the use of recombinant DNA technologies have made the research that they support which is related to various diseases move ahead more rapidly.

The investments in such basic research made 10 or more years ago and continuing over this past decade, largely with NIGMS support, are now being used not only to study diseases, but also by a wide range of industries to improve, among other things, agricultural production. In addition, drug companies are taking advantage of this technology to make new pharmaceutical products, as well as to dramatically improve the quantity, efficacy, and purity of currently used therapeutic agents.

New and similar studies are now being performed using these tools of basic research. This will help the United States maintain its scientific leadership into the 21st century.

NIGMS has supported the development of nuclear magnetic resonance [NMR] spectroscopy which Dr. Goldstein of the National Institute of Neurological and Communicative Disorders and Stroke just mentioned to you. We saw NMR start as an originally very exotic technology, and we have watched it become an extraordinarily powerful tool which will facilitate progress in virtually all areas of biology and medicine. NMR is being used to examine the detailed structure of chemicals in the body, for example.

Genetic tools, such as recombinant DNA technology, are providing further details of chromosome and gene structure. Scientists have been exploring how such structure accounts for the function of genes as a blueprint for the human body—a blueprint that is in each one of the cells that makes up the body. One of the most important questions to which we seek an answer is how certain parts of this blueprint are selected by certain tissues and certain cells to be expressed at specific times, while others lie dormant. This is one of the central questions that basic research must try to answer.

You heard from Dr. Goldstein, and you heard from me last year, about the enormous progress being made regarding Huntington's disease. The techniques that were used to find the marker that is associated with the Huntington's disease gene are called gene mapping and chromosome walking. NIGMS grantees developed these techniques, which are now being used to study other genetic diseases about which

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we know almost nothing, except that they cause devastating illness and disability, diseases such as cystic fibrosis, neurofibromatosis, and others.

As we have learned more and more about our genes, we also have to learn more about our cells. The cell is the fundamental unit of all living organisms. We now know, just as Dr. Lipsett of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases indicated to you, that cells have, on their surfaces receptor molecules which recognize and bind specific agents, such as chemicals, hormones and enzymes It is only after this recognition and binding has occurred on specific sites on the cell membrane that a specific response can be triggered. Scientists are learning how to specifically tailor or design chemicals so that they can be recognized more easily, more rapidly, and more efficiently by the receptors on the cells. This is particularly important in the production of important chemicals using biotechnology.

What has made this enormous progress possible has, of course, been the creativity of the Nation's biomedical scientists. It is a creativity which has been enhanced by the excellence of the research training that they have received. As you probably know, a recent publication of the Institute of Medicine-National Academy of Sciences has indicated that scientists who received support for their doctoral research training from NIH fare better in their subsequent research endeavors than do others who have not been so supported, and indeed those supported by the National Institute of General Medical Sciences do even better.

Mr. Chairman, I will be happy to answer any questions.

ROLE OF NIGMS

Senator WEICKER. As I understand, you are the underpinning here, or the first-step foundation for what proceeds in the various other institutes.

Dr. KIRSCHSTEIN. That is true.

Senator WEICKER. Are you involved in this AIDS situation?

Dr. KIRSCHSTEIN. We are not involved specifically in research related to AIDS. However, the basic molecular biology that has allowed dissection of the immune response and brought to fruition of the studies of virology leading to the isolation of the virus of AIDS as well as recombinant DNA technologies that eventually will make it possible to produce a vaccine, are all the products of the basic studies supported by NIGMS.

Senator WEICKER. What concerns me is that your efforts are really key to everything else that follows, yet I don't think that it is as easy to explain to the public what it is that you are doing. I am really concerned about this budget of yours. Indeed, it will impact down the line on the efforts of the others. That is my concern.

Dr. KIRSCHSTEIN. Yes, sir; we do indeed need the basic underpinnings provided by basic research in order to assure that continued progress will be made as it has been in the past. In the period of the late 1960's and 1970's, as the advances in genetics and cell biology came about and as recombinant DNA technology developed, no one had the slightest

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idea of how rapidly the applications of these advances would be possible.

For instance, Dr. Fauci of the National Institute of Allergy and Infectious Diseases told you that in a record short time, we have been able to go from development of basic knowledge to almost the first trial of a vaccine. We have been making progress toward increased applications of basic biomedical findings much more rapidly than any of us ever thought would be possible.

In addition, we are very pleased that the American public does indeed understand the importance of basic biomedical research. It is of interest that a recent Harris poll found that 82 percent of the people who were surveyed believe that even if there are no immediate benefits, scientific research is an endeavor worth supporting. We are very pleased by this finding because we know that it is through basic research that progress will be made.

RESEARCH TRAINING

Senator WEICKER. The NIGMS funds the major portion of the research training awards made by NIH. The training budget requested by NIH for fiscal year 1986 supports the same number of trainees as fiscal year 1985 but does not contain any adjustment for tuition increases and institutional costs, which I would imagine are quite substantial in the area of medicine.

How is this going to translate insofar as the persons involved, the numbers of people involved?

Dr. KIRSCHSTEIN. The request is for the same number of dollars as in 1985, hopefully to support the same number of trainees.

Senator Wicker. How are you going to do that?

Dr. KIRSCHSTEIN. We are going to try.

Our experience has been that tuition has been increasing at about 9 percent per year from 1972 to about 3 or 4 years ago. Recently, those increases have accelerated to about 11 to 14 percent a year. So there are indeed substantial tuition increases.

What we try to do is to support the finest students in predoctoral education at the finest institutions, in multidisciplinary research training programs, so that when they finally enter their research careers, they can concentrate their efforts in any one of a number of fields where the most important scientific opportunities might lie.

Senator WEICKER. You are talking about cutting about 10 percent in the number of individuals who will receive the training, if the tuition costs are going up, and they are, and the funds are the same.

Dr. KIRSCHSTEIN. This was one of the difficult decisions that had to be made.

Senator WEICKER. I understand that, but what we are saying is that we are going to have about 10 percent fewer people.

Dr. KIRSCHSTEIN. That is possible, although it is not what is projected in the budget.

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The other thing was that there were increases provided last year by the Congress, as you know, to increase stipends, and the stipend levels have also gone up.

SUPPORT OF MINORITY INSTITUTIONS

Senator WEICKER. I know of the Institute's interest in supporting individual minority research careers. Last year Congress added $10 million to help minority institutions strengthen institutional participation in the biomedical research.

Can you review for us your Institute's participation in both of these programs?

Dr. KIRSCHSTEIN. The minority research centers program to which you refer is under the aegis of the Division of Research Resources [DRR], and I am sure that Dr. Pickett, the Director of DRR, will be talking about that when she testifies.

The NIGMS contribution to efforts affecting minority institutions is in the area of research training. We have a program called the minority access to research careers [MARC], through which we support individuals at the undergraduate level, as well as at the predoctoral and postdoctoral training levels. These are individuals at minority institutions.

We feel that the most important thing that we can do to begin the process of stimulating individuals is to provide background training at the college level, in the junior and senior years, for honor students who will then go on to research careers. We have been training a large number of these minority undergraduate students since 1975. To date, about two-thirds of the graduates of this MARC Honors Undergraduate Research Training Program have gone on to graduate and professional education.

We are especially pleased that a number of them are participating in both graduate programs and the combined M.D./Ph.D programs which, we believe, will lead to fruitful research careers.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. I have further questions for response to the record. We very much appreciate your testimony.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

BASIC RESEARCH

Question: The NIGMS supports basic non-disease targeted research. Other Institutes, of course, tend to focus their support on specific disease entities. Why is the kind of research you support important?

Answer: The research supported by the NIGMS is extremely important, in that our grantees are the developers of the new concepts and technologies which are utilized and expanded upon by the investigators working on disease-targeted studies. Very often, a researcher has an idea--for determining, let us say, the mechanisms which affect the secretion of a particular protein. In its inception, such a project may not have obvious importance to a specific disease. The NIGMS would fund this type of study. However, as the investigator's research progresses, it may be discovered that something important is being learned about a particular disease, such as cystic fibrosis. For example, it may be found that the body does not produce enough of the protein in question, or perhaps produces defective copies of that protein--findings which would be of great importance to an understanding of the cause of that disease. At that stage, the research project, or perhaps the findings produced by that project, would be picked up and expanded upon by the appropriate categorical institute; in this case, NIADDK.

Question: Can you give us an example or two where basic research supported by your Institute has opened up new opportunities for other institutes--cancer for example?

Answer: As noted in the General Statement accompanying our budget justification for Fiscal Year 1986, the discovery of oncogenes --genes which can trigger the onset of cancer--would not have been possible without the development of recombinant DNA technology by NIGMS grantees. Similarly, long-term support provided by the NIGMS was critical to the development of nuclear magnetic resonance (or NMR), instrumentation mentioned by most of the directors of the institutes appearing before the Committee this year because of its great potential in a variety of research areas, including medical diagnosis.

Question: How would you judge the payoff to the taxpayer?

Answer: The payoffs for the taxpayer are enormous, and not only in the field of medicine. For example, the genetic engineering research pioneered by NIGMS grantees is at the heart of America's growing new biotechnology industry, which is already having an impact on areas as diverse as mining, agriculture, and the production of pharmaceuticals. This translates into jobs--4,500 today in Montgomery County, Maryland, alone--and a healthier economy, as well as healthier Americans.

BASIC RESEARCH/NEW DEVELOPMENTS

Question: We have been hearing about the value of research in basic molecular biology and virology and the "clinical spinoffs" that have occurred. Can you give us a recent example of such a spinoff?

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Answer: Basic research discoveries in the field of molecular biology are developing a number of important clinical spinoffs in the virology area, in regard to the diagnosis, treatment, and prevention of viral infections. Indeed, molecular biology is providing us with many powerful new clinical tools that researchers believe will eventually allow us to deal much more effectively with disease-producing viruses. For example, new, highly sensitive tests are now being developed for detecting viral nucleic acids and viral antigens in tissues; and, in many cases, such tests can be carried out with great speed, using only small amounts of materials. Information being developed on the basic molecular structure of viruses (their nucleotide sequences) is also providing a basis for the production of a whole new generation of vaccines. To date, improved vaccines for hepatitis B, influenza, and herpes simplex viruses have been developed in this way and have already been tested in animals.

Question: I understand that research in this area has been greatly enhanced by the development of "new tools." What are some of these "new tools" and what do they mean for future research?

Answer: The new "tools" to which you refer are research techniques made possible by the advent of recombinant DNA technology. Using such techniques as "gene reassortment" (the systematic exchange of genes from one variant of a virus to another), the cloning of viral genes, and gene mapping, investigators have been able to "molecularly dissect" viruses, and then relate their genes and gene products to a number of virus disorders.

Exactly how viruses manage to change the function of cells or cause cell death is still not totally clear; but studies performed to date indicate that there are specific viral genes which determine the route of an infection, and others which determine the precise tissue to be infected. This knowledge of how genes specify the characteristics of a virus will, undoubtedly, lead to more effective approaches for interfering with the harmful activity of a virus and to progress in the prevention and treatment of these infections.

Question: Has your Institute been involved in these developments?

Answer: NIGMS grantees have played a very important role in the development of most of the new recombinant DNA-based technologies and approaches now being used across the broad range of biomedical research fields. Typical of this are advances in "in situ hybridization" techniques developed by NIGMS grantees, which are critical to the now widely used gene mapping process; i.e., the process of identifying on a chromosome the precise location of a gene which is responsible for either a normal or abnormal effect.

GENETIC ENGINEERING

Question: We have been hearing a lot about genetic engineering --predictions of biological revolution and predictions of biological disaster. Can you give us a brief review of what the future holds in this area?

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Answer: For centuries, a simple form of genetic engineering has been practiced in agriculture to make sure that the best plant and animal strains are used. However, most recently, genetic engineering has come to be the term used synonymously with recombinant DNA technology, a technique which allows scientists to combine genes or pieces of genes from different organisms. Recombinant DNA technology allows geneticists to isolate the gene for a biologically useful substance, such as human insulin, and insert it into a microbial host, such as a bacterial cell. Bacteria containing the insulin gene will then produce large quantities of human insulin, which can be collected and used to treat diabetic patients. To date, insulin, growth hormone, interferon, and other medically important substances which are difficult or expensive to obtain by other means have been successfully produced by genetic engineering. Similar methods are being used to produce therapeutic agents, such as "tissue plasminogen activators," which promise to reduce mortality from heart attacks; vaccines; and diagnostic reagents. In the future, further practical applications of recombinant DNA technology to address medical problems can be expected, as can additional uses in biomedical research itself.

Genetic engineering also holds great promise in agriculture for the production of plants which are disease- and pest-resistant, which can produce greater yields, which contain a higher level of nutrients, which can be grown in non-fertile areas, such as the sub-Sahara desert, or which are salt-tolerant and can be irrigated with brackish water. Genetic engineering can also produce larger and healthier livestock, through the development of improved vaccines to prevent disease and through the introduction of growth-promoting genes.

Question: What about the dangers we hear about?

Answer: In the early 1970s, when gene cloning experiments were first undertaken, scientists considered the possibility that this type of genetic manipulation might pose hazards to health or to the environment. Although no danger had been demonstrated, there was no certainty in those early years that genetic engineering would be completely safe. Safeguards were formulated by an international group of molecular biologists, and restrictions were placed on the conduct of certain types of experiments. The Recombinant DNA Advisory Committee (RAC) was set up at NIH to establish guidelines and to judge the acceptability of experiments using recombinant DNA technology. To date, thousands of recombinant DNA manipulations have been performed under the NIH guidelines; there have been no untoward consequences.

Question: Do you feel that controls are adequate?

Answer: Several features of recombinant DNA technology combine to make potential risks extremely small. First, recombinant DNA, as an isolated material in a test tube, is not dangerous. It can only be transferred into living cells under carefully controlled conditions. Second, bacteria used in any type of experimentation almost never escape from laboratories and cause infections. Third, the bacterial strains used in genetic engineering were developed so they would not survive well outside the laboratory, because most require special nutrients for growth. Finally, scientists have realized

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that genetic recombination occurs in nature without man's interference and is not in itself dangerous.

Controls on genetic engineering are still imposed by the Recombinant DNA Advisory Committee, as well as by the Environmental Protection Agency and the Food and Drug Administration, when genetically engineered products involve release into open environments or involve the use of pharmaceuticals. Although these controls are adequate, it is important that the public be well informed and the scientific community, responsible and accountable.

BIOPHYSICS AND PHYSIOLOGICAL SCIENCES PROGRAM

Question: I understand that you have been working to improve the Physiology and Biomedical Engineering Program. Can you describe the scope of that program and elaborate on its long-term goals?

Answer: The previous Physiology and Biomedical Engineering Program has recently been reorganized into the new Biophysics and Physiological Sciences (BPS) Program. Part of the rationale for this reorganization has been the rapid growth in recent years of research in the biophysical sciences, and the need to provide a focus within NIGMS for such research.

The program consists of a Biophysics Section and a Physiological Sciences Section. The Biophysics Section, which also includes bioengineering, involves the application of physical principles to biological research, as well as the translation of these efforts, through engineering, into practical applications. Instrument development is also supported by this Section. Long-range goals include the understanding of the structure of biological macromolecules, and the way such structure influences biological activity.

The Physiological Sciences Section encompasses research related to burn and trauma, as well as studies in general physiology at the organismic level. The trauma and burn research is attempting to understand the systemic, total body response to injury, using the methods and approaches of biochemistry, physiology, and microbiology.

Question: How will these improvements aid the newly developing biotechnology industry?

Answer. The research conducted in this program, primarily in biophysics, provides the basic underpinning to the biotechnology industry. For example, progress in the development of new instrumental techniques, such as nuclear magnetic resonance and mass spectrometry, have led to the formation of numerous small companies which are exploiting these advances for industrial or medical applications. In another area, fundamental information on the structure and function of proteins is being applied by biotechnology companies to the selective production of proteins having specific useful properties.

In short, the basic research supported by this program has had many practical applications, very few of which could have been predicted in advance.

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TRAINING COSTS

Question: The NIGMS funds the major portion of the research training awards made by NIH. The training budget requested by NIH for FY 1986 supports the same numbers of trainees as FY 1985 but does not contain any adjustments for tuition increases and institutional costs.

Do you have any data on the rate at which tuition increases and other trainee expenses have been increasing in the past few years?

Answer: Data on tuition charges at institutions receiving training grants from NIGMS indicate that tuition increases in recent years have ranged between 9 percent and 13 percent per year.

Question: Who absorbs these extra costs?

Answer: During the typical 5-year life of a training grant, funds from one grant budget category--such as trainee-related expenses--may have to be shifted to the tuition category to cover these increased costs. At the time when such grants successfully compete for renewed funding, NIGMS has to allocate the funds necessary to meet the increased tuition costs.

Question: The universities do benefit from the training programs. Is it reasonable to expect them to share in some of the costs?

Answer: Universities share in the costs of these programs in a number of ways. First, the universities make a major contribution by providing faculty salaries, laboratory space, equipment, and supplies. This is a significant expense for research training grants, since the indirect costs paid by the Federal Government may not exceed 8 percent. Second, about one-half of the graduate students in any given research training program are supported by the university on teaching assistantships, research assistantships, university fellowships, and other mechanisms; NIGMS provides funds for the other half of the trainees.

PRIVATE SECTOR SUPPORT OF SOME RESEARCH

Question: Of all the basic research supported by your Institute, I would think that the area of pharmacological sciences would attract interest from the private sector. Does the pharmaceutical industry share some of the costs of this research? If so, how can we enhance these types of cooperation?

Answer: The pharmaceutical industry shares some of the costs of certain types of basic research in a variety of ways. (1) The Pharmaceutical Manufacturers Association Foundation (PMAF) is a non-profit foundation run by the Association to provide pre- and postdoctoral fellowships, as well as salary support for new investigators and research starter grants in pharmacology. A large number of grantees in the Pharmacological Sciences Program have benefited in the past or are currently deriving benefits from this program. (2) The Burroughs-Wellcome Company Foundation provides a wide range of fellowships in many areas related to the pharmacological sciences but especially in clinical pharmacology. Many of the clinical

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pharmacology research training programs supported by the NIGMS Pharmacological Sciences Program are enriched by being in an environment in which there is a Burroughs-Wellcome award for the development of clinical pharmacology. (3) The G. D. Searle Company runs the Searle Scholars Program and provides untargeted research funds to outstanding young investigators. One of the grantees of the Pharmacological Sciences Program is currently a Searle Scholar.

In addition to these general support and development programs, many investigators have grants from one of a number of pharmaceutical companies to study agents of special interest to that firm. Dr. Arthur Atkinson at Northwestern University has been studying the orphan drug, NAPA, and has been working closely with at least two drug companies in its development. He has just recently been successful in finding an industrial sponsor to market the drug. Dr. Nicholas Bodor at the University of Florida recently received a multi-million dollar grant from industry to develop "soft drugs"—drugs that remain in an inactive form until they reach their target organ. This is an extension of the type of research he originally did with support from NIGMS.

It is especially important to enhance the more undifferentiated types of cooperation such as provided by the Burroughs-Wellcome Foundation, the PMAF, and the Searle Scholars Program. These programs allow for the maximum development of the individual and give persons so supported the greatest flexibility to follow promising areas of research. Perhaps the best way to foster this cooperation is to increase the already existing communication among the industry-sponsored programs, the scientific community and the branches of government which support the relevant areas of research. One way this is being done currently is by making more members of the scientific community, especially the younger population just finishing their research training, aware of the opportunities that those foundations provide.

TRAINING

Question: I note that you are not requesting an increase in the number of trainees funded by your Institute. In fact you are training 135 fewer than the number trained in 1984. Are you already training enough trainees? If not, how many should your Institute be training?

Answer: In 1974, Congress enacted the National Research Service Act which provided for an ongoing examination and review of the supply and demand for research manpower in this country. This responsibility was given to the National Academy of Sciences (NAS), which has published annual, and more recently, biannual, reports of its studies, deliberations, and recommendations. The NIH and the National Institute of Mental Health are particularly noted as contributors in the area of biomedical research training, and the recommendations of the NAS address the overall question of how many individuals ought to be supported by these agencies. No specific allocation is made to individual institutes.

The NAS recommendation with regard to numbers of trainees and fellows is made with the assumption that, in the absence of support for this number, there may well develop a general shortage of

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biomedical investigators 5-10 years from now. The current budget falls slightly short of the NAS recommendations, but these recommendations are, of course, only guidelines and estimates. With the historic allocation of NIH trainees, NIGMS would support about 3,666 if the NAS recommendations were followed.

Question: You have made reference to the study by the National Academy of Sciences which found that individuals trained with support from your Institute are more likely than comparison groups to have successful careers in biomedical research. What is it that you are doing right, and is it transferable to other Institute training programs?

Answer: The NIGMS predoctoral training grants have been very successful, providing for the development and maintenance of broad, fundamental research training programs in the basic biomedical sciences and including the best biomedical faculty and students at the leading universities and medical schools across the country. The goal of this program is to provide a multidisciplinary research training setting with a strong emphasis on quality. The NIGMS staff, acting on the advice of peer review groups, work hard to ensure that funded programs live up to these ideals of high quality.

It is not clear that the multidisciplinary predoctoral training grant format would be suitable for the categorical Institutes, which have research training missions focused on more specific clinical areas.

PRIORITY SETTING

Question: Your Institute covers a broad spectrum of research into the basic mechanisms of biology and medicine. What mechanisms are in place to set the research priorities at NIGMS?

Answer: The basic, undifferentiated research supported by NIGMS is focused on a continuum of interlocking scientific problems, the solutions to which may come from a number of different directions in unexpected ways. Critically important conditions for progress in these areas are: (1) scientific opportunity, which is dependent on the availability of creative scientific talent with requisite research training, (2) key experimental data and findings, and (3) appropriate instrumentation. In our experience, the best judges of these factors are the working scientists, themselves, whose career incentives are clearly connected to success in making significant discoveries and who can therefore be relied on, generally, to propose germane research projects. Consequently, the key factor in setting research priorities for the studies supported by NIGMS is the scientific merit assessment by the peer review system.

Furthermore, the Institute's Advisory Council provides informed oversight, by reviewing the Institute's allocations of support to its various programs in an ongoing fashion and offering comments and recommendations, as well as reviewing all research grant applications. The Council has to approve each grant application before it may be funded. The Council is particularly on the lookout for emerging scientific areas or inappropriately neglected areas that would warrant greater emphasis.

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Question: How do you use the Director's discretion to fund innovative proposals out of sequence?

Answer: Innovation and originality are much prized by scientists, generally, and recognized as almost essential ingredients for a proposal to be judged meritorious by the peer review system. It is therefore only on rare occasions that the Director or the Institute staff have to intervene for this reason. However, if such an occasion arises, I do provide funds for the award of such proposals upon the advice of the Institute staff and the Advisory Council.

Question: Can you give us some examples of successes that have occurred because you chose to use your discretion?

Answer: A possible example of such a case would be a program project on the molecular and cellular basis of behavior, conducted by Dr. Eric Kandel (New York State Office of Mental Health). This proposal had received a priority score below the general payline. Recognizing the great scientific promise in a cellular and molecular approach to the study of behavior, the Institute did fund this application. Dr. Kandel's continuing contributions to this field were recognized when he received the Lasker Award for Basic Research in 1982.

Another example would be that of Dr. James McCloskey, of the University of Utah, whose research project grant application on the mass spectroscopy of nucleic acids was rated beyond the general payline in 1977. Nevertheless, because we considered this to be a very innovative effort, it was funded. Competing renewal applications in 1980, and again in 1983, were rated as excellent by the study section involved, with comments that it was important research which had contributed to the entire field of nucleic acid chemistry, and was shedding light on the biologic role of DNA.

FIVE-YEAR GRANT CYCLE

Question: There has been recent discussion about changing from a three-year grant funding period to one of five years in length. What is your position on this proposal?

Answer: Under current NIH policy, a grant funding period can be anywhere from one year to five years. The average length of a grant award is, however, just over three years. The length of each grant award is determined primarily by the recommendations of the peer review group. It is my position that currently too many grants are awarded for only three years. We believe that an investigator of proven productivity, who submits a highly meritorious application, should normally receive a five-year grant. However, in many instances, a three-year grant also is appropriate, as for example, when an investigator's track record is not yet well established or when the proposed research will not take more than three years to complete.

Question: What are some of the benefits and disadvantages of this proposal?

Answer: The benefits of a longer grant award are stability for

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the research group supported by the grant, time savings from not having to write up and submit as many applications, and the ability of the investigator to tackle problems that may be risky and may not pay off until more than three years of work have been invested in them. The disadvantage, of course, is that projects which do not work out may continue to be funded for five years without additional peer review. It is, therefore, in my opinion, important to reserve the five-year grants for the best investigators and the most exciting projects.

SENIOR SCIENTISTS TURNOVER

Question: A large number of your senior-level scientists have expertise in technical areas with a "high market value," for example, recombinant DNA. Is your Institute having difficulty in attracting and retaining these individuals?

Answer: There have been a number of times in recent years when we have experienced difficulty in recruiting or retaining senior-level scientific staff for important leadership positions in our scientific programs.

Question: What are the effects within the various laboratories when such a person leaves the Institute?

Answer: While it is from our extramural scientific programs, rather than from laboratories, that NIGMS loses such staff, the loss of a key senior scientist has, I suspect, a similar effect: it results in a period that could be characterized as a "holding action." Uncertainty, rather than assertive leadership, marks the period until a suitable replacement can be found. Because these senior scientists possess extraordinary expertise and enjoy such high respect from their peers in the scientific community, their absence leaves a very real void in directing the grant programs of the Institute.

Question: What can NIGMS do to remedy the situation?

Answer: Because, most typically, the senior scientists who leave NIGMS or decline to accept positions with the Institute either are getting or can command higher salaries than government service can offer, there is very little that NIGMS can do to remedy this situation.

Question: How many of these individuals are you losing?

Answer: NIGMS has a small staff of senior scientists, about 15, who direct our scientific programs. In recent years, we have lost one or two of these people per year to retirement or to other institutions and, when recruiting for replacements, have often had difficulty attracting suitable candidates.

Question: What kind of salary increases are being offered to these senior people?

Answer: In our experience, senior-level scientists outside the government earn at least one and one-half to two times the salary possible in government service, and they frequently also enjoy

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better benefit packages. For instance, within the past six months, an eminent pharmacologist, whom we were trying to entice into a Senior Executive Service position at NIGMS, turned us down because the salary we could offer was less than half his present salary at a university medical school.

"PREVENTIVE" RESEARCH

Question: In a speech before the American Pharmaceutical Association, Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: In a real sense, almost all of the Institute's support should be regarded as contributing to prevention of disease or its complications. The rationale for supporting basic biomedical research is to acquire a better understanding of the causes of disease and the biological mechanisms involved in the development of disease. Only when a reasonable understanding of the pathogenesis of disease is at hand can real progress be made in prevention.

Question: What percent of your budget is directed to preventive research?

Answer: In a more circumscribed sense, prevention research is supported by NIGMS in the area of clinical genetics and counseling; clinical pharmacology and the study of ways to minimize adverse drug reactions; and the area of trauma and burns, where the objective is to prevent complications. These three areas account for about $2.7 million, or 0.7 percent of the total research budget for NIGMS.

Question: How are the results of this research being translated into useful public information?

Answer: The primary audience for the findings of most of the prevention-relevant research mentioned above, is the community of practicing physicians, which quickly incorporates corroborated research findings into daily practice. Through scientific meetings and publications, such research is disseminated to physicians throughout the country. The translation and transfer of this knowledge to the patient, where appropriate, are carried out by the individual physician.

OMB DIRECTIVE

Question: Dr. Kirschstein, the OMB directive has requested that you not fund 99 continuing research projects and 137 newly approved research projects. By restricting the number of new projects, are you preventing the exploration of newly found avenues of research?

Answer: Yes, necessarily. However, we will be funding 776 new and competing grants and a total of 2,663 research grants. A great deal of promising research will proceed through these grants.

Question: Can you give us a few examples and possibly project the long-term effect of such ill-advised policy?

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Answer: The NIGMS supports basic research studies in a number of fields where very exciting research is now being done, and where the emerging opportunities for advances in knowledge can be expected to stay ahead of the dollars to exploit them for many years to come. This is most especially true in the fields of genetics and cellular and molecular biology, to which we have allocated over 70 percent of our available funds. It is also true, to almost the same extent, in other areas supported by the Institute, such as biophysics and pharmacology. The immediate effect of supporting fewer new awards in 1985 than previously projected is really a slowing down of the pace of discovery in all these fields, as well as perhaps some missed opportunities. The long-range effect, of course, is extremely hard to predict.

Question: What kinds of effects does the loss of a long-standing reapproved project have on the science and scientist?

Answer: Some of the principal investigators on these projects may be able to obtain limited resources either from the Biomedical Research Support funds at their institutions (provided by the Division of Research Resources, NIH) or from private sources. Undoubtedly most of these scientists will also submit additional grant applications to NIH and others, in hopes of securng continued full funding of their research efforts.

Question: Have you made your views known to the Administration?

Answer: Since the NIH is an agency of the Administration, these actions had been preceded by discussions and careful considerations at appropriate levels.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: In NIGMS, the administrative costs for our extramural activities amount to 2.8% of our total budget. Even though these costs are minimal, NIGMS is continuing, as it has in recent years, to look for and implement administrative efficiencies. The overhead category in which the most significant savings have been achieved and productivity increased is personnel. While the grant workload for NIGMS has almost doubled in the past 10 years, our extramural staffing level during that same period has held relatively steady at a modest 138-143. While some additional savings in the personnel category may be possible, it is important to maintain sufficient scientific, administrative, and support staff to assure proper stewardship of grant funds. Additional computerization of some activities, appropriate contracting out of certain tasks, streamlining some administrative processes, and belt-tightening in areas such as travel and consultant services may yield some further savings. To some extent, the need to expend funds for grant administration is beyond our control because workload demands depend on the number and types of grant proposals submitted for consideration by NIH.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

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Answer: The Executive Officer, NIGMS, and his staff are charged with analyzing how the Institute plans and carries out its work, and whether our work methods and procedures can be improved to achieve economies. They frequently make recommendations to me in this regard. In addition, we cooperate in and make suggestions to various trans-NIH groups responsible either for developing or recommending ways to improve administrative efficiencies both in the institutes and in the central service components of NIH.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: In recent years, I have used the annual management reviews which I hold with my senior staff to discuss how our workload could be redistributed or altered as personnel leave the Institute, so that some vacancies need not be filled. We have achieved some staff reductions as a result. Other savings in personnel costs have been achieved by tightly controlling overtime. In a number of particularly labor-intensive areas, we have begun to rely more heavily on the computer to save both time and the need for added personnel in the face of increasing workload. Furthermore, to the maximum extent possible, we are taking advantage of the increasing number of either government-wide or NIH-wide service and supply contracts--such as those for specific airlines, express delivery services, office supplies, and equipment repair--to achieve savings.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: Like the other institutes and divisions at NIH, the NIGMS takes its peer review responsibilities very seriously. Thus, in looking for and implementing various cost-saving measures, we take special care to avoid compromising the thoroughness and equity of the review of the research and research training grant proposals which are referred to the Institute. The number of NIGMS staff responsible for grant review activities and the number of NIGMS initial review groups remain the same as in recent years. Since the attention of staff and review committee members is the key to sound peer review, we are confident that our other cost-cutting measures--such as in equipment, supplies, and services--will not be harmful to the review process.

PRIORITIZATION OF RESEARCH

Question: What role does the NIGMS Advisory Council play in the prioritization of research? How is research priority decided upon within the Institute? Is there a correlation between the areas of expertise of the members of the Advisory Council and what research areas are prioritized?

Answer: The members of the National Advisory General Medical Sciences Council are the senior advisors to the Institute Director, the Director of NIH, and the Secretary of DHHS in regard to the support of basic undifferentiated biomedical research and research

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training. The scientific programs of the NIGMS are presented by the Institute staff to the Council members, who discuss all facets of the broad array of research and research training relevant to the Institute's mission and play a critical role in recommending priorities. The Advisory Council, over the past ten years, has indicated that the priority areas for research support should be genetics and cellular and molecular biology. Within the past year, the members of the Council, after a thorough review, recommended that NIGMS establish a separate program of support for research in biophysics. This suggestion was based on evidence that the field of biophysics was burgeoning and that great progress had occurred in the recent past, and could be anticipated in the future.

In addition, the National Advisory General Medical Sciences Council has reviewed the Institute's activities in support of research training and had an important influence on their direction. The Council has recommended that the research training priorities be set as follows: first, multidisciplinary institutional predoctoral research training grants; second, individual postdoctoral fellowship awards; and third, postdoctoral institutional research training grants. The Advisory Council has also made recommendations regarding the relationship of the unique Medical Scientist Training Program of NIGMS to the other research training supported by NIGMS.

The members of the Advisory Council, in addition to helping to set Institute priorities, are specifically charged to perform the second level of review of grant applications. They are appointed by the Secretary, DHHS, based on the requirements and expertise needed to perform such reviews, as well as to set priorities. It is important to emphasize that, in addition to the scientific experts who serve on the Council, one-third of the members are "lay" participants whose "expertise" is in the arena of knowledge and concerns regarding the importance of biomedical research and research training to the health of the American people and the diagnosis, treatment, and prevention of disease. These "lay" members play an important role in the setting of research priorities.

Questions Submitted by Senator William Proxmire

NUCLEAR MAGNETIC SPECTROSCOPY

Question: Dr. Kirschstein, in your prepared testimony you refer to nuclear magnetic resonance (NMR) spectroscopy as an exciting and versatile new technology. You also point out that one of your grantees, Dr. Paul Lauterbur, has done some award-winning work in the development of NMR for diagnostic imaging.

As you know this instrumentation is very expensive. Each device costs millions of dollars. Having supported investigations into its use as a diagnostic tool, do you feel any responsibility for taking part in the crafting of guidelines that determine when its use is appropriate and what level of use would justify the acquisition of the device by a hospital or a doctor?

Answer: The research related to NMR supported by NIGMS has been of a very basic character, and is now and has been primarily directed toward its use in other research endeavors. The evolution of this

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methodology into a clinical diagnostic tool could not have occurred without this foundation, but, after Dr. Lauterbur's initial studies, much of the practical development has occurred in industry. Since the thrust of this Institute is almost exclusively in basic research, we do not feel that we have the expertise to consider either questions of cost containment or guidelines for use.

RESEARCH CENTER GRANT FUNDING

Question: Last year you estimated expenditures of $10,221,000 on 17 research centers in fiscal year 1984. You ended up funding 18 centers but spending only $9,304,000--a cut of about 14 percent in the average cost of operating a single center. Can you tell us what happened to change those costs so dramatically?

Answer: The increase from 17 to 18 awards was actually due to the award of a competing supplementary grant to one of the already existing 17 research center grants. The total number of research center grants thus remained at 17, as initially requested. Consequently, the reduction in the average cost of a center grant was only 9 percent over that originally estimated. The National Institute of General Medical Sciences is committed to the research center grant programs we support, but we also insist that all our center grants maintain the highest quality of research both in terms of the center as a whole and in terms of each project within the center grant. As applications come in, they receive critical peer review by the study sections and by the National Advisory General Medical Sciences Council. If any component projects are not up to the standards we expect, they are usually deleted from the budget during peer review. In Fiscal Year 1984, we found that the applications we received did not have as many meritorious subprojects as we had hoped and, therefore, the size of the grants that were awarded was smaller than we had originally anticipated.

Question: Dr. Kirschstein, on page 4 of last year's justifications you indicated you planned to devote $1,760,000 in fiscal year 1985 to three pharmacology-toxicology centers. Although we gave your Institute a hefty increase, your most recent justifications show a budget of $1,603,000 for those centers in fiscal year 1985. I wasn't aware that the Congress had cut your initial request in this area. Can you tell what caused the reduction?

Answer: The explanation for the discrepancy you have identified in the pharmacology research center grants budget is similar to the one that I gave you for the National Institute of General Medical Sciences centers program as a whole. At the time the 1985 budget was put together, we made dollar projections regarding our pharmacology research center grant program, based on the dollars that we thought would be requested in each of the expected applications as well as those in the commitment base. We used our best professional judgment in calculating both what grant applications might be expected and what the amount of each center grant award would turn out to be. As the applications actually came in and proceeded through the peer review process, certain projects within the centers were disapproved, and the budget figures therefore changed. Although we do our best to anticipate what these budget changes will be, we are not, of course, always able to predict them with precision.

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Question: According to last year's justifications, in 1984 you planned to allocate $1,801,000 to these three centers. You actually spent $1,486,000. What factors produced this miscalculation?

Answer: The factors which influenced the Fiscal Year 1985 totals also resulted in the difference between our Fiscal Year 1984 estimates and the final obligation figures.

RESEARCH CAREER PROGRAM

Question: You also had a dramatic shortfall in your research career program. Instead of making 27 awards in 1984, as you planned to do last year, you only made 19 awards. Why did you cut the program by almost one-third?

Answer: The research career program consists of two parts--the research career awards and the research career development awards. The former are salary awards to outstanding senior investigators that continue until the end of each investigator's research career. Although these awards are no longer made by NIH, several previously made awards are still ongoing. Last year, three such awards were terminated unexpectedly due to the death or retirement of the principal investigator.

Research career development awards are made by the National Institute of General Medical Sciences only in areas that bridge the gap between basic and clinical research. Although we feel it is important to attract investigators into these areas, we have not been able to attract as many applications as we would like and as we had planned. We did fund all the meritorious applications that were received in Fiscal Year 1984.

CELLULAR AND MOLECULAR BIOLOGY

Question: Dr. Kirschstein, your opening statement focuses on the work you are doing with regard to basic cellular and molecular biology. This year the National Science Foundation will obligate about $112 million for molecular and cellular biosciences grants, targeting about $16 million of this total on genetics research. Can you tell us the factors that determine whether research in this general area is supported by NIH or by NSF?

Answer: The primary distinction between NIH and NSF programs is that the research supported by the NIH must be health related, whereas research supported by the NSF need not have such a relation to health. Despite this, there are, of course, cases where research proposals qualify for either NIH or NSF support, and we recognize this. To avoid any duplicate funding, our professional staff maintains a very close working relationship with the staff of the NSF, and we share information on the research grant applications which each of us receive and award.

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NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

STATEMENT OF DR. DUANE ALEXANDER, ACTING DIRECTOR

ACCOMPANIED BY:

DR. JAMES R. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

JOEL R. HEDETNIEMI, EXECUTIVE DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. Last, we will hear from Dr. Duane Alexander, Acting Director of the National Institute of Child Health and Human Development.

Dr. Alexander, it is a pleasure to have you before the committee. We will insert your statement in the record and then you may proceed.

[The statement follows:]

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STATEMENT OF DR. DUANE ALEXANDER

Mr. Chairman and members of the Committee, the mission given the NICHD by Congress is, in its simplest terms, to ensure through research the birth of healthy babies, the birth of wanted babies, and the opportunity for each infant to reach adulthood unimpaired by physical or mental handicap and able to achieve his or her full potential. No mission could coincide more closely with the dreams and aspirations of the American people and indeed the whole human family--this is what we all want for our children.

Though this dream is closer to realization today than 22 years ago when Congress established this Institute, we still have a long way to go. The infant mortality rate has been cut by more than half in this country during this time, due in large part to advances from research supported by this Institute. Nonetheless, 11 countries have a lower rate. The rate among blacks is still double that among whites, and the rate of low birth weight (LBW) has not changed. Although 95 percent of sexually active American women use some form of fertility regulation at some time, surveys indicate that more than half (52 percent) of the six million pregnancies each year are not wanted at all or not wanted at the time they occur. As for opportunity, of our 3.6 million infants born each year, nearly 40,000 die before their first birthday, 250,000 face an increased likelihood of handicap as a consequence of low birth weight, 3 percent have a significant congenital anomaly, another 3 percent are mentally retarded, and approximately half will need medical treatment for serious injury during their childhood, often with lasting physical or mental consequences. Our researchers are confident that they can find ways to improve these outcomes.

Low Birth Weight

Last year, in presenting NICHD's testimony before this Committee, Dr. Mortimer Lipsett outlined a new Low Birth Weight Prevention Research Initiative developed by the Institute to address the most important problem in maternal and child health in the U.S. Two-thirds of all infant deaths occur among those weighing less than 5 1/2 pounds at birth, incidence of handicap among survivors is high, and direct costs for neonatal intensive care of these infants exceed $2 billion annually. I am happy to report that the initiative is under way. In December the first women were recruited for our Vaginal Infections and Prematurity study, a large clinical trial in which we will screen more than 15,000 pregnant women for asymptomatic vaginal or urinary tract infections, and for those infections thought to be associated with LBW, determine whether antibiotic treatment will reduce the incidence of LBW.

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Better Babies Project

Scientists in our epidemiology program have helped design and initiate a study of prevention of LBW in the District of Columbia called The Better Babies Project. Located in an area of the city where the incidence of LBW exceeds 15 percent, compared to 7 percent nationally, the aim is to determine whether outreach to identify women early in their pregnancy and link them to existing medical services, combined with interventions to improve nutrition and social support services and reduce smoking, alcohol, and drug abuse, can reduce this high incidence of LBW. Most of the funding comes from private sources, with NICHD supporting data collection and analysis. This is an example of cooperation between government and the private sector to achieve common goals.

Last year our epidemiologists also identified two additional risk factors for LBW. First, mothers who themselves were LBW are two to three times more likely to have a LBW infant than women who were normal in weight at birth. Second, women who consume as few as one or two alcoholic drinks per day during pregnancy substantially increase their risk of having a LBW infant.

In 1985, we will fund a new center focused on the problem of intrauterine growth retardation, one cause of LBW, and begin studies attempting to develop biological predictors of women who are highly likely to deliver a LBW infant.

Networks

From the funds we are requesting for FY 1986 we plan to initiate two LBW research networks under cooperative agreement grants. One will be a network of six maternal/fetal medicine units around the country that will develop common protocols and conduct studies of obstetric management focused on LBW prevention. The second will be a network of six neonatal intensive care units that will develop common protocols and assess ways to improve the management of sick and LBW newborns. Combining scientific teams in this manner will provide us with the large numbers of patients needed to answer important questions about LBW as quickly and economically as possible.

The work we are doing on LBW prevention is the key to the nation's effort to reduce further our infant mortality rate and ensure the birth of healthy babies. This is a top priority of the Institute.

Injury Prevention

What about helping children achieve their potential? The most important child health problem following infancy is injury. From age one throughout childhood more children die from injury than any other cause; in fact, more than the six next leading causes combined. Many non-fatal injuries cause

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permanent disability. With the encouragement of this Committee, which last year requested that we develop a special report on injury prevention, and of the American Academy of Pediatrics, we have developed two special solicitations for grant proposals related to injury prevention. One focuses on studies of risk-taking behaviors, antecedents of injury, and behavioral interventions to prevent injury. The second, in the Institute's Small Business Innovative Research solicitation, tries to enlist the untapped inventiveness in small businesses in America to develop devices or methods that will reduce childhood injury. Our appropriation request for FY 1986 includes funds for these efforts.

Growth and Development

Our scientists are addressing many other problems of childhood as well. The most remarkable characteristic of childhood is growth. Two years ago we reported to this Committee the exciting developments in gene transfer technology that were permitting manufacture of human growth hormone (GH) by bacteria, providing a virtually unlimited supply of this previously scarce hormone so that more short children could achieve near-normal height. We thought then that this was the ultimate answer, but it wasn't. Our scientists who in 1977 won the Nobel Prize for identifying brain chemicals that stimulate the pituitary to release its hormones recently identifed growth hormone releasing factor (GRF). Our initial studies with this substance indicate that eight out of ten children classified as GH deficient are actually GRF deficient, and grow better with treatment with GRF given to stimulate their own pituitary to release GH than by giving injections of GH. We know that it is possible to make analogs of other brain hormones to increase their potency, and with some of the FY 1986 funds requested, we will be trying to do that with GRF also.

Birth Defects

That is one example of a direct payoff from years of basic research. The same is happening in other NICHD laboratories where the techniques of the new biology are being exploited as rapidly as possible. Studies of genetic control of early development will yield clues as to the origin of birth defects. Basic neurobiologic studies of cell-cell interaction, early formation of the nervous system, programmed cell death, cell regeneration, and neurotransplantation hold hope for understanding and preventing mental retardation. Gene therapy looks ever closer and more promising as a way to deal with some of the most devastating disorders of childhood. We have just funded a grant to develop the means to transfer a gene to correct Lesch-Nyhan syndrome, characterized by profound mental retardation and self-mutilating behavior. This is the

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first grant at NIH specifically targeted toward human gene therapy, with studies to be conducted in animals including non-human primates, in order to reach a state of readiness for human work. That research will continue with the funds requested for FY 1986.

Improved Vaccines

Marked improvements in laboratory techniques are also allowing scientists in our intramural program to develop improved vaccines for infectious diseases. Pertussis has recently become a major public health problem because of concerns about the safety of the present vaccine. Our intramural scientists have identified the pertussis toxin as the factor responsible for the disease and for inducing immunity, and have developed ways to grow the organism in large quantities, extract the pure toxin, treat it chemically to create a harmless but immunogenic toxoid, and make a vaccine using the toxoid. We hope to begin a field trial of this improved pertussis vaccine in the fall, using funds requested for FY 1986. This same laboratory has also developed a markedly improved typhoid vaccine. While not a major problem in this country, the disease is endemic in many third world countries, with a significant loss of life. We are beginning field trials of this vaccine this year in Nepal and South Africa.

Infertility

What are we to do to assure wanted babies? The NICHD is the world's largest source of support for research on basic reproductive science, infertility, contraception, and social and behavioral sciences related to population. As one example of our efforts to help infertile couples have the children they want, Scientists in our intramural program have developed a treatment for hypogonadotropic hypogonadism, a condition in which the pituitary gland does not produce the hormone necessary to stimulate sperm formation. In the NICHD program, 27 babies have been fathered by previously infertile men. This number will be multiplied many times because this treatment is being used now in medical centers around the world.

Population Studies

Although involuntary infertility affects 10 percent of couples, the larger reproductive issue is prevention of unwanted pregnancy. Recall the statistic I mentioned earlier: 52 percent of pregnancies in this country are unwanted at all or at the time they occur, despite the availability of contraception. This means that we need better contraceptives, a public better informed on their correct use, and an understanding of how to enhance appropriate use. The worldwide importance of this issue, and some recent developments in our basic

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reproductive sciences research program that hold promise for totally new and better approaches to contraception, led the Institute to assemble a Contraceptive Development Initiative comparable to the Low Birth Weight Initiative described earlier, and coinciding with a major project by the American College of Obstetricians and Gynecologists on prevention of unintended pregnancy. In this initiative, we plan to follow up the indications that immunization against specific components of sperm or egg is possible and develop a research program in immunocontraception. Our scientists have characterized two natural products made by the body, called inhibin in the male and folliculostatin in the female, that interfere with sperm and egg production. We plan to pursue these leads aggressively, as well as look for other natural products that may have similar effects. Recently an FDA expert committee advised that Depo-Provera, a long-acting injectable contraceptive, not be licensed for use in the United States. We currently have under development a markedly improved second generation drug comparable to Depo-Provera but apparently without its adverse side effects. We plan to expedite the testing of this compound, along with other drug delivery systems, including injectables, skin patches, and a disposable spermicide-releasing diaphragm. Funds to begin these efforts are included in our FY 1986 request.

Complementing this biomedical research will be a series of behavioral studies focused on reasons for use or non-use of contraceptives and choice of method. We also plan a major conference to present the latest findings on safety of the new lower dose oral contraceptives to dispel some of the unfounded public fears about the pill.

Summary

Mr. Chairman, the research supported by this Institute affects the quality of life for every American, directly impacts on the aspirations of parents for their children, and through its emphasis on prevention is highly cost-effective. Our success in achieving our child health goals will affect the health, well being, and productivity of our adult population, and our success in population research will play a major role in the future of life on this planet. The 1986 budget request for this Institute is $293,084,000, a decrease of $17,002,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985, this Institute will fund 421 new and

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competing grants of which 51 will receive 3 years of support. In addition, we will fund 42 centers, of which 1 will receive 2 years of support.

I will be happy to answer any questions.

Biography of Dr. Duane Alexander

BIRTH	August 11, 1940, Baltimore, Maryland
MARITAL STATUS	Married Marianne Ellis, Washington D.C., June 23, 1963; two children
EDUCATION	Pennsylvania State University, University Park, Pennsylvania, B.S. Degree, Pre-Medical), 1962
	Johns Hopkins University School of Medicine, Baltimore, Maryland, M.D. Degree, 1966
INTERNSHIP	Intern and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1966-1967
RESIDENCY	Assistant Resident and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1967-1968
MILITARY SERVICE	1968-1970: Surgeon (LCDR), U.S. Public Health Service, and Clinical Associate, Children's Diagnostic and Study Branch, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland
	1971-Present: From Surgeon to Medical Director, U.S. Public Health Service
FELLOWSHIP	Fellow in Pediatrics (Developmental Disabilities), John F. Kennedy Institute for Habilitation of the Mentally and Physically Handicapped Child, Johns Hopkins Hospital, 1970-71
LICENSURE	Maryland Board of Medical Examiners
CERTIFICATION	Diplomate, American Board of Pediatrics, 1973
POSITIONS HELD	
1971-74	Assistant to the Scientific Director, National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland
1974-78	Medical Officer (Staff), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW
1978-82	Assistant to the Director, National Institute of Child Health and Human Development, National Institutes of Health
1982-Present	Deputy Director, National Institute of Child Health and Human Development, National Institutes of Health
1985-	Acting Director, National Institute of Child Health and Human Development, National Institutes of Health

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INTRODUCTION OF ASSOCIATES

Dr. ALEXANDER. Thank you, Mr. Chairman.

I am accompanied by our Executive Officer, Mr. Joel Hedetniemi.

Twenty-two years ago, when Congress established our Institute, you asked us to conduct and support research to accomplish three goals: First, healthy children; second, wanted children; and, third, that children would reach adulthood free from physical and mental handicap.

The prepared statement I submitted for the record documents some of our progress toward these goals, and I will take just a couple of minutes to highlight some of the things in that statement.

LOW BIRTH WEIGHT PREVENTION

First, the birth of healthy children. The major problem here is low birth weight. Last year, Dr. Lipsett outlined to you our proposal for a low birth weight prevention research initiative, and with the funds that were provided, that initiative is under way. One of the special efforts in this area is a large clinical trial to detect and treat asymptomatic vaginal and urinary tract infections in pregnancy to try to prevent low birth weight. We are doing that study in collaboration with the National Institute of Allergy and Infectious Diseases.

In addition to that, we are working with the D.C. Government and the private sector in a better babies project, trying to reduce the rate of low birth weight by identifying pregnant women earlier and providing the best that we know how in maternal health care and support services.

We are also going to be supporting a new research center on intrauterine growth retardation this year.

In fiscal year 1986, we plan to establish networks of neonatal intensive care units and maternal/fetal medicine units to facilitate the conduct of clinical trials in preventing low birth weight and treating low birth weight infants.

CONTRACEPTION

As for unwanted children, our surveys indicate that over 50 percent of pregnancies in this country are not wanted. To increase our efforts in addressing this problem, we are proposing a contraceptive development initiative to translate new findings from our basic reproductive sciences research to clinical applications. This includes new efforts in immunocontraception, developing naturally occurring inhibitors of sperm and egg maturation as contraceptives, and developing a longlasting injectable contraceptive.

We also plan behavioral studies focusing on reasons for use, nonuse, or incorrect use of contraceptives.

This effort closely relates to the low birth weight initiative in that unwanted pregnancies are more likely to result in babies of low birth weight.

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CHILDHOOD INJURY PREVENTION

Finally, a safer and healthier childhood. Injuries are the leading cause of death throughout childhood, as well as a major cause of physical and mental handicap. With the encouragement of this committee, we are soliciting grant applications for behavioral studies on prevention of childhood injuries.

PERTUSSIS VACCINE

Finally, much attention has been focused recently on the pertussis vaccine as a cause of disability. Adverse reactions to currently used vaccines are rare, but fear of reactions is creating a large public concern. Our intramural scientists are working on developing a markedly improved pertussis vaccine. The one that we are developing has only one component, a pure chemical toxoid from the bacteria. We believe that this vaccine is going to be effective and will be virtually free of side effects. We plan to initiate field trials this fall.

In these ways, Mr. Chairman, we are working to fulfill our goal, a goal that is identical with the goal of all parents for their children. Our research emphasizes prevention, and is highly cost effective.

INFANT MORTALITY AND LOW BIRTH WEIGHT

Senator WEICKER. I have asked my staff to bring down to me a very thorough article that appeared in the New York Times today on this matter of low birth weight and infant mortality. Again here, I think a very confusing picture has been left by virtue of the testimony that we have received from the Institute, the testimony that we have received from the Secretary's office, and the testimony that we have received from the public.

I will say that it roughly comes down in the following way, which is that we have rather optimistic reports from the administration as to the decline in infant mortality rates, that compared to what I would say is rather alarming testimony from health directors, especially in urban areas, where they have great numbers of minority poor.

The thrust of the article today, or most of it, was that the decline in infant mortality rates has slowed considerably in the last couple of years. That is sort of the bottom line of this article, the decline has slowed somewhat. Obviously, people such as myself attribute that, in some measure, to the administration's cutback of funds for prenatal care, et cetera. The administration clearly takes the other point of view, they would probably dispute the statistics.

I think that I have fairly synopsized the confusion that exists here in this area. It should be a matter of enormous concern to the Nation as a whole, and certainly to the administration, with the unborn. Here we have a problem that would indicate that we are far from a satisfactory solution. I would like to hear you comment a little more.

This is an article by Robert Pear about what causes the high rate of infant deaths.

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Federal officials and public health experts are asking why, in an age of medical miracles, the decline in the Nation's infant mortality rate has slowed perceptibly. They are expressing concern that 6.8 percent of all babies—12.4 percent of black babies—are low weight, that is, under 5.5 pounds, at birth. Research has demonstrated conclusively that the risk of death increases as birth weight decreases.

Doctors are asking other questions, too: Why, when science is continually finding new ways to prolong life for the elderly, do nearly 40,000 American babies die each year in the first 12 months of life? And why is the infant mortality rate for blacks still, as in 1965, almost twice the infant mortality rate for whites?

For the interrelated problems of infant mortality and low birth weight, many of the solutions are already known to medical experts.

The Institute of Medicine, as part of the National Academy of Sciences, said in a report last month: "Policy makers and health professionals know enough at present to intervene more vigorously to reduce the incidence of low birth weight in infants. Methods already available have demonstrated their value in reducing low birth weight." The same is true for infant mortality, because anything that reduces the incidence of low birth weight helps reduce the incidence of infant death.

[The full text of the article follows:]

[From the New York Times, Mar. 20, 1985]

What Causes High Rate of Infant Deaths?

(By Robert Pear)

WASHINGTON, March 19.—Federal officials and public health experts are asking why, in an age of medical miracles, the decline in the Nation's infant mortality rate has slowed perceptibly. They are expressing concern that 6.8 percent of all babies—12.4 percent of black babies—are low weight, that is, under 5.5 pounds, at birth. Research has demonstrated conclusively that the risk of death increases as birth weight decreases.

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The Institute of Medicine, as part of the National Academy of Sciences, said in a report last month: "Policy makers and health professionals know enough at present to intervene more vigorously to reduce the incidence of low birth weight in infants. Methods already available have demonstrated their value in reducing low birth weight." The same is true for infant mortality, because anything that reduces the incidence of low birth weight helps reduce the incidence of infant death.

Using advanced technology, doctors have been able to save tiny babies and those born with physical defects that would have been fatal just a few years ago. However, physicians and other experts say the Nation could do more, much more, to reduce infant mortality through basic, preventive medicine and public education to highlight the need for early prenatal care and the risks of smoking, drinking or taking drugs during pregnancy.

Several factors coverged last month to focus attention on the issue. The Public Health Service reported that the infant mortality rate appeared to be stabilizing at slightly less than 11 deaths for each 1,000 live births, after declining steadily from a level of 24.7 in 1965.

Dr. Edward N. Brandt, Jr., who served as Assistant Secretary of Health and Human Services in the first 4 years of the Reagan administration, described the data as "disquieting" and "worrisome."

The data have been mentioned at several congressional hearings, where lawmakers were investigating possible effects of cuts in the Medicaid budget proposed by Mr. Reagan.

The administration is in a delicate position, wanting to publicize the need for prenatal care while trying to reduce the growth in Federal health spending for the poor. In-

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fant mortality is a volatile political issue. Some administration officials say that if they publicized the problem in an effort to solve it, they might play into the hands of their political opponents. These critics, such as the Children's Defense Fund, among others, contend that the administration's economic and social policies have exacerbated the problem.

Stephanie Lee-Miller, an Assistant Secretary of Health and Human Services, said today that "the Department has no response at this time" to the charge that its policies had affected the infant mortality rate. Margaret M. Heckler, the Secretary of Health and Human Services, plans to discuss the issue at a news conference Friday, when she issues the Department's annual report on national health statistics.

Some career scientists in the Public Health Service acknowledge the possibility that cutbacks in Federal programs serving women and children might have affected infant mortality. But senior officials at the Department of Health and Human Services generally do not accept that there is any connection. One official said that smoking, drinking, and drug abuse by pregnant women were more important factors than the budget changes.

The concern about infant mortality is bipartisan. It was a Republican Governor, Thomas H. Kean of New Jersey, who said in a speech last month: "The most painful death in all the world is the death of a child. When a child dies, when one child dies—not the 11 per 1,000 we talk about statistically, but the one that a mother held briefly in her arms—he leaves an empty place in a parent's heart that will never heal."

Governor Kean, who is chairman of the National Governors Association Committee on Human Resources, said that infant deaths were "most often the result not of genetic faults, not of inadequate medical knowledge, not of disease, but of social factors—poverty, age, race, nutrition, and substance abuse."

Governor Kean said that one way to deal with the problem was to "expand eligibility" and "increase benefits" under Medicaid, the Federal-State health program for low-income people. While many States are cutting back on Medicaid, Governor Kean said he was seeking an expansion of the program in New Jersey to provide prenatal care and other services to more women.

Southern Governors last year formed a task force on infant mortality headed by Gov. Richard W. Riley of South Carolina, a State with one of the highest infant mortality rates (15 deaths per 1,000 live births). "Paying for high-tech medical rescues, as opposed to prevention, is a poor method of investing our health dollars," said Mr. Riley, a Democrat.

His report, which cited the work of many researchers, said that "Preventive prenatal and infant health care more than pays for itself." By reducing the number of unhealthy babies, the report continued, "prenatal and infant care can save $2 to $10 for every preventive dollar invested."

The Public Health Service said the mortality rate for infants in the first month of life continues to decline, in part because of the sophisticated medical technology available in neonatal intensive care units. But the mortality rate for older infants, in the next 11 months of life, appears to have increased, and the Public Health Service expressed "serious concern" about this.

Deaths in this "postneonatal period" had been considered more preventable because, as the southern Governors said, they often result from "external factors such as inadequate food or sanitation, unsafe housing, and lack of infant health services."

While the mortality rate for babies in the first month of life has dropped sharply in the last 15 years, there has been no comparable decrease in the incidence of low-weight births.

Many factors that increase the risk of low birth weight are well known and can be minimized in a program of comprehensive prenatal care, the report said. For example, doctors and other health professionals can warn women of childbearing age, before they become pregnant, about the dangers associated with smoking and alcohol and drug use, the study said. They can also identify problems such as hypertension and malnutrition before they become serious.

Prenatal care has proved beneficial for all women, but particularly for those at high risk: teenagers, women age 35 or older, those with less than 12 years of formal education, unmarried women, members of racial minotirites, and low-income women.

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The Institute of Medicine study group, headed by Dr. Richard E. Behrman, dean of the medical school at Case Western Reserve University in Cleveland, lamented "the Nation's patchwork, nonsystematic approach" to providing prenatal care. Neither the Federal Government nor the States are responsible for making sure that such services are available to people who need them, it said.

The panel suggested several ways to increase access to prenatal care, including "greater reliance on certified nurse-midwives and nurse-practitioners."

The Public Health Service has set these goals for 1990: The infant mortality rate should be no higher than 9 deaths for each 1,000 live births, and no racial or ethnic group should have an infant mortality rate exceeding 12 per 1,000. (For blacks in 1982, the rate was 19.6, as against 10.1 for whites.)

The Public Health Service says that low-weight babies should account for no more than 5 percent of all live births in 1990. (In 1982, as in each of the two previous years, they accounted for 6.8 percent of live births.)

In addition, the Public Health Service says that no more than 9 percent of the infants born in any racial or ethnic group should have low birth weight. (For blacks in 1982, the proportion was 12.4 percent, as against 5.6 percent for whites.)

Some doctors say it becomes progressively more difficult to reduce the infant mortality rate as it declines to lower levels.

But Sam Shapiro, a professor at the Johns Hopkins Univesity School of Hygiene and Public Health, said that a "leveling off" of the infant mortality rate was not inevitable after a series of decreases. "Other countries have reached lower levels than the United States," he said, "and experience suggests that lower levels elsewhere indicate achievable levels here."

ABILITY TO SAVE LOW BIRTH WEIGHT INFANTS

Senator WEICKER. It is a very thoughtful article. I have been asking the same questions, not only in conversations with Dr. Lipsett, but more importantly in questions directed at the Secretary and those within her organization in charge of the programs that might impact on this disaster.

Is the article correct in saying that this decline has slowed perceptibly?

Dr. ALEXANDER. That statement is absolutely correct.

Senator WEICKER. Taking it from that point, what in your opinion do we have to do?

Dr. ALEXANDER. There are several factors. Much of the decline in infant mortality that has occurred over the past 10 years, and this is documented in the Institute of Medicine report, has come as a result of our improved ability to save the low birth weight infants.

It may be that we are now reaching the limit of our technology in saving those low birth weight babies, and we need to increase our efforts on prevention of low birth weight in the first place. In the time that low birth weight has been reported in this country as a vital statistic, it has only declined from 7.6 percent in 1950 to 6.8 percent at this time. At the same time, infant mortality has declined by more than one-half.

I think the conclusion is that we are reaching our limits in our ability to save these tiny, low birth weight infants, and we need to increase our emphasis on preventing low birth weight.

Senator WEICKER. That would clearly relate to prenatal care.

Dr. ALEXANDER. It relates to prenatal care primarily, but also to pre-

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pregnancy care, child spacing, and wanted pregnancy, all of which correlate very highly with low birth weight. In a wanted pregnancy, the low birth weight incidence is about 4.4 percent. In the unwanted pregnancy, it is about 7.3 percent.

PRENATAL CARE

Senator WEICKER. Counsel points out to me it may be as much a problem in another part of the budget where they are cutting down the funding for the community health centers which relates directly to prenatal care, and certainly that would coincide with the testimony of the health directors of various cities where they indicate that part of the problem is the first time they ever see the mother is when she is wheeled into the hospital in labor. Then you compound that problem with the privatization of hospitals in this country to where there are only a few places where anybody can go. You can start to see how all of this impacts on these statistics.

Dr. ALEXANDER. A related concern in infant mortality is that, along with the slowdown in the decline of the infant mortality rate, we seem to have stopped our increase in rate of women receiving any prenatal care. The portion of women who are beginning prenatal care in the first trimester seems to be leveling off as well. That is a concurrent concern we have, and something that we hope to address as part of the efforts that we are making in low birth weight prevention.

MENTAL RETARDATION RESEARCH CENTERS

Senator WEICKER. How many mental retardation centers are now in operation?

Dr. ALEXANDER. There are 12 mental retardation research centers supported by this Institute.

Senator WEICKER. How do they fare under the 1986 request?

Dr. ALEXANDER. The centers line will stay constant under the fiscal year 1986 request. The estimate for the mental retardation research centers stays at $9,432,000 in both fiscal year 1985 and 1986.

Senator WEICKER. What do these centers do?

Dr. ALEXANDER. These centers are a valuable national resource in our efforts to develop means of preventing, treating, and ameliorating mental retardation. Many of them are interdisciplinary centers that try to blend research in the biomedical area with behavioral research. The research focuses on determining the basic causes of mental retardation, including a considerable amount of work in basic neurobiology and substantial work in genetics. Research in the behavioral sciences deals with adaption of the child to the community, improving the learning capabilities of the retarded child, and improving the capabilities of families to deal with and adapt to the presence of the retarded child in the family.

Senator WEICKER. You say that there are 12 of these centers.

Dr. ALEXANDER. That is correct.

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Senator WEICKER. What is the patient population of those centers? Do they actually have youngsters there at the centers, or is this strictly doctors, scientists, et cetera?

Dr. ALEXANDER. All of these centers have some degree of clinical programs; none of them, however, are in-patient facilities. Many of them are associated with the university affiliated facilities in mental retardation. Ten of the 12 centers are affiliated with those.

Senator WEICKER. Do you have a list of those?

Dr. ALEXANDER. We can provide that.

Senator WEICKER. The number of personnel who are involved, and the number of out-patients that they involve themselves with.

[The information follows:]

MENTAL RETARDATION RESEARCH CENTERS

The 12 mental retardation research centers [MRRC's] supported by the NICHD are as follows:

TITLE AND LOCATION

Research in Mental Retardation and Child Development, University of Washington, Seattle.

Support for Mental Retardation Research Center, Yeshiva University, New York, NY.

Program for a Research Center in Mental Retardation, University of Kansas, Lawrence.

Child Development and Mental Retardation, University of North Carolina, Chapel Hill.

Center Grant for Research in Mental Retardation, University of Colorado, Denver.

Research in Mental Retardation, E.K. Shriver Center for Mental Retardation, Inc., Waltham, MA.

Mental Retardation Research Center, University of California, Los Angeles.

Mental Retardation Research Program, Children's Hospital Corp., Boston, MA.

Wisconsin Center for Mental Retardation, University of Wisconsin, Madison.

Core Grant for Mental Retardation, University of Chicago, Illinois.

Center for Research in Mental Retardation and Human Development, Vanderbilt University.

Biology of Down Syndrome, University of California, San Francisco.

It is estimated that these 12 centers serve approximately 106,000 patients, with staffs that total 802 professional and 1,355 support personnel.

It should be noted that the number of patients reported above does not convey the full picture of services provided by the MRRC's. Considerable outreach activity is also involved. This activity and the provision of technical assistance is characteristic of most centers which provide a critical mass of expertise with outreach capabilites.

DOWN SYNDROME

Senator WEICKER. Do any of the centers get into the matter of Down syndrome?

Dr. ALEXANDER. Yes; several of the centers have active programs in Down syndrome. The Vanderbilt center in particular has an active component in Down syndrome.

Senator WEICKER. Is there anything new in that area?

Dr. ALEXANDER. Some of the studies that they are working on include work on the language development of Down syndrome children, work with the families in increasing language stimulation, particularly very

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early language stimulation, in Down syndrome children. Results indicate that this does produce beneficial effects and improves language and communicative ability in these children. That is one of the studies being done at the Vanderbilt center.

One of our centers focuses specifically on Down syndrome; this is a specialized research center in San Francisco. It is working primarily on the mouse model of Down syndrome.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. I will have some further questions to be answered for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

GENETIC THERAPY

Question: Genetic research has been identified as an area where we may expect major breakthroughs in the treatment of disease. I understand that you have been talking about gene therapy. Have you developed gene therapies that can modify or treat genetic defects?

Answer: Much additional research is needed before gene therapy will become a reality. At the present time there are no gene therapies that have been adequately developed and proven effective for use in the treatment of genetic defects. Current therapy is focused on symptoms and secondary defects through the use of surgical and pharmaceutical treatments. However, the Lesch-Nyhan Syndrome is considered a good candidate for continuing study and future gene therapy. This inherited disease has been targeted because it is caused by a single gene mutation, is incurable and frequently is lethal. This therapy would attempt to alter the gene functions of some body cells in the patient, but would not involve cells that are used in reproduction. Strategies for other genetic diseases are even less well developed at this time, but therapy of Lesch-Nyhan disease may serve as a model approach for a variety of inherited diseases.

Question: Are we funding enough research in this area?

Answer: At the level of the budget request we will continue to make adequate progress in this area. Some research is aimed at developing strategies for gene therapy, and a considerable amount of other research is relevant to understanding the processes of gene therapy.

WHOOPING COUGH VACCINE

Question: I understand that your Institute is working on developing a better vaccine for Whooping Cough (Pertussis). Will this vaccine be safer than the one currently being used, and why is that so?

Answer: The pertussis vaccine developed by the Laboratory of Developmental and Molecular Immunity at NICHD is expected to produce fewer adverse effects than the vaccine currently in use. Research in this area suggests that one protein contained within the pertussis organism, a toxin, produces the symptoms of whooping cough and also induces the antibodies which subsequently protect the child against the disease. Therefore, a vaccine containing an inactivated pertussis toxin should be highly protective, but have fewer side-effects than the current DTP vaccines which contain unnecessary components. The new vaccine has as its only component the inactivated toxin, or "toxoid." This toxoided vaccine produces an excellent immune response in laboratory animals, and has no detectable adverse effects. A field trial is planned to begin in November 1985 and will determine whether the new pertussis vaccine provides greater protection with fewer adverse effects than any other vaccine available.

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INFERTILITY

Question: We have heard that problems of infertility affect about 10 percent of the population. What kind of success have you had in treating male infertility?

Answer: Infertility is not a reported disease in this country and, as such, no accurate estimate of its incidence exists. Infertility among couples includes reproductive problems resident in either the wife or husband. A liberal definition of the term is lack of pregnancy during one year of attempt. Because infertility is a heterogenous group of disorders, treatment success rates will vary. We estimate the overall treatment success to be 50 percent, but reproductive disorders in women are more successfully treated than those in men. Treatment success among men is greatest in patients with anatomic lesions, such as obstruction of the ducts which carry sperm. These lesions account for perhaps 10 percent of the men who are known to be infertile. However, congenital disorders of the testis, and testicular damage from drugs and toxins, are generally not reversible. At least half of the men who are infertile have disorders of sperm production or sperm function, for most of which specific therapy is not yet available. NICHD intramural scientists have found that a small subgroup of men, 0.1 percent of male infertility, have pituitary hormone deficiency which can be readily corrected, leading to a high fertility rate. Such medical therapy, however, does not appear to be effective in treating men with infertility of unknown cause. For this latter group, new developments in the laboratory will be required to identify specific biochemical causes of the abnormal sperm function.

Differential diagnosis of male infertility has improved with the availability of newer technologies to better assess hormonal status as well as other factors which contribute to infertility in men, e.g., sperm autoimmunity, sexually transmitted diseases, and genetic disorders of reproduction.

Several additional points are worthy of note. Detailed surveys of reproductive impairment among married couples in the United States, performed as part of the National Survey of Family Growth by the National Center for Health Statistics, indicate progressively reduced fertility among couples who are in their later reproductive years, 30s and 40s. Thus, infertility appears to affect increasingly larger numbers of couples who postpone a family in order to achieve additional education and professional careers. Infertility specialists also note that in about 5 percent of infertile couples the problem can be traced to inadequate understanding of coital techniques or ovulation timing.

Question: Have the children of parents who have been treated with hormone therapies been followed?

Answer: Children of the small subgroup of fathers with congenital hormone deficiency are at risk for the same genetic disorder as their parents. Such children will be followed carefully at NICHD to determine if their own puberty is delayed. If so,

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medical therapy is available for these children as it was for the parent who required that therapy in order to be fertile.

In the past few years, a variety of hormonal preparations have been widely used to induce ovulation in infertile women. We do not know of any large scale studies of the offspring of women who received such therapy. However, there is now an increasing subpopulation of this group of women who are induced to ovulate specifically for in vitro fertilization and embryo transfer. A study is now being developed by NICHD to examine these children for possible disorders. We understand that similar studies will soon be initiated in Great Britain.

Question: Have you found any cause for concern in these children?

Answer: All children in our intramural treatment studies are less than 10 years old at the present time and as such, they are too young for us to determine accurately whether they will have pituitary hormone deficiency. We estimate that 30-50 percent may require hormone therapy similar to their affected father. Pituitary hormone replacement has not been associated with significant side-effects either in the treated fathers or in the offspring resulting from the treatment.

If there is an adverse effect on offspring of women who become pregnant after receiving drugs to induce ovulation, it is estimated by our epidemiologists to be very small.

CONTRACEPTIVE RESEARCH

Question: We have been told of breakthroughs in contraceptive research. Can you describe these breakthroughs and tell us what they may lead to?

Answer: The contraceptive development initiative the Institute has proposed highlights the most exciting and fruitful areas of current and near-future research. One area in which we are presently testing products is long acting injectable contraceptives. We have two approaches, one using microcapsules and the other a biodegradable rod-shaped polymer. Both slowly release the drug at a steady rate, are effective for one to two years, and do not require removal. Another injectable is a safer substitute for Depo-Provera. We are about to begin testing skin patches as alternative and potentially safer delivery systems for contraceptives, and a disposable spermicide-releasing diaphragm.

Our program of basic research in the reproductive sciences has recently provided exciting new leads that we want to exploit for contraceptive development. Our scientists have demonstrated that it is possible to stimulate antibody production against numerous components of sperm and egg, so we plan to expand this work in a program of immunocontraception, in essence to develop a "vaccine" against pregnancy. Other investigators we support have identified natural products made by the body, inhibin in the male and folliculostatin in the female, that specifically interfere with

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sperm formation or ovulation. We plan to expand our work with these substances as potential contraceptives. Our work in receptor biology suggests that it may be possible to block the action of the pituitary hormones, LH and FSH, that induce spermatogenesis and ovulation, by blocking the testicular and ovarian receptors for these hormones. We will be pursuing research in that area as well.

Question: Have you found a contraceptive that would work in countries of the third world?

Answer: Although our research is focused on the needs of the American public, we do know that there are similarities in contraceptive practice among the various countries. It is our belief that a long-acting injectable contraceptive formulation or an implant on which we are currently doing research will be particularly useful in some of the developing countries.

LOW BIRTH WEIGHT BABIES

Question: More than 200,000 low birthweight babies are born in this country each year. What can you tell us about the initiative begun last year on the prevention of low birthweight babies?

Answer: In 1984, the National Institute of Child Health and Human Development began a major special initiative--an expanded research program in the prevention of low birth weight. There have been some interesting findings in various research projects. Studies have shown that the mother's own birth weight is directly related to the birth weight of her child. Also it has been determined that the ingestion of as few as one or two alcoholic drinks per day during pregnancy does have an effect upon lowering the birth weight of the infant. Studies are being carried out to elucidate the factors that might account for clear differences in birth weight among ethnic groups, especially a black-white difference. It is known that blacks are twice as likely to have a low birth weight child. Research supported has included studies of hormonal control of fetal growth, prenatal and neonatal function of specific hormone-secreting glands, and the role in fetal growth regulation and labor initiation of hormones secreted by the placenta. A long-term research project is examining the development of fetal thyroid function, the responsiveness of various tissues to the hormone, and the thyroid's role in normal fetal growth and development. Other studies have further documented the role of maternal smoking in contributing to low birth weight, and that mothers who stop smoking during pregnancy reduce their chance of having a low birth weight infant.

Current activities of NICHD in the area of low birth weight encompass the following:

(1) Plans to fund a center grant on intrauterine growth retardation. Applications have been received and the evaluation of their scientific merit is in process;

(2) Plans to fund two networks as cooperative agreements, one involving neonatal intensive care units and the other involving maternal/fetal medicine units that will address

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clinical research questions in high-risk populations. The request for applications has been published with the submission date of June 14, 1985;

(3) Initial funding of a program project on diet of high risk pregnant women in the District of Columbia, including the role of diet in preventing low birth weight;

(4) Continued support of meritorious research in areas concerned with fetal growth factors, biological predictors of fetal growth, and premature labor;

(5) Support of an ongoing contract study entitled "Prevention of Prematurity by Detection and Treatment of Gestational Genitourinary Infections: A Multicenter Randomized Controlled Clinical Trial." Studies are being carried out in 5 centers;

(6) Expansion of an education effort targeted to high-risk women and physicians. Some of the topics to be addressed include early entry into prenatal care, smoking as a cause of LBW, and recognition of signs of early labor to permit intervention.

Question: Has there been any indication of improvement in the numbers of low birthweight babies born each year?

Answer: The percentage of all live births weighing less than 2500 grams, approximately 5 1/2 pounds, for the entire U.S. are as follows: 6.8 percent in 1980, 6.8 percent in 1981, 6.8 percent in 1982. The percentages for white births are 5.7 percent, 5.7 percent and 5.6 percent in 1980, 1981 and 1982 respectively. Among blacks, the percentage of all births that are low birth weight is 12.5, 12.5 and 12.4 in 1980, 1981 and 1982. Thus, in the early 1980s there was little change. Tabulations for 1983 are expected later this year.

Question: Is there a connection between the incidence of low birth weight babies and the method of contraception used by the parents?

Answer: Large prospective studies of the association between the use of contraceptives prior to and around the time of fertilization have shown little association between contraceptive usage and low birth weight. The largest of these studies was conducted by NICHD in the 1970s, and included 34,000 pregnant women in the Northern California Kaiser Permanente Health Plan. The women were followed prospectively to evaluate the effects of contraceptive usage on birth outcomes. Among women who used contraceptives during the six months prior to becoming pregnant the low birth weight rates were: 4.2 percent for oral contraceptives, 2.8 percent for the IUD, 3.3 percent for spermicides, 3.9 percent for barrier, 4.2 percent for rhythm, 3.3 percent for other forms, and 5.1 percent for non-users. Although contraceptive users tended to have a slightly lower frequency of low birth weight than contraceptive non-users, this difference is more likely due to other differences among the various groups of women rather than to the contraceptives themselves.

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SENATE MANDATED LOW BIRTH WEIGHT CENTER

Question: Last year this Committee provided funds for a specialized research center for low birthweight babies. Has this center been created or has it fallen to the OMB Directive?

Answer: In FY 1985 the Institute is planning to fund one new center for research on intrauterine growth retardation.

Question: Where is the center located and how much funding will it receive in FY 1986?

Answer: The center has not yet been chosen since applications for this grant will not be reviewed by the National Advisory Child Health and Human Development Council until September. It is estimated that funding for this center will be approximately $700,000 in FY 1985, and approximately the same amount in FY 1986.

LOW BIRTH WEIGHT/PRENATAL CARE

Question: Last year you informed the Committee that the number of pregnant women seeking and getting prenatal care has increased. Is that still the case?

Answer: From 1970 to 1980 the percent of women seeking prenatal care increased. The National Center for Health Statistics reports that the latest data for 1981 and 1982 show an actual slight decline in use of early prenatal care.

Question: Has your Institute involved itself in education programs that inform the public of the importance of prenatal care?

Answer: The NICHD is involved in a variety of efforts to inform the public of the importance of prenatal care. Several pamphlets are available from the Institute on this topic. The Institute is also assisting in the design and evaluation of the Better Babies Project, an intervention trial to reduce the rate of low birth weight in the District of Columbia. The target area for the project averaged 15.5 percent low birth weight deliveries during the period of 1980-1982. The city wide rate for that same period was approximately 13 percent. The national rate for LBW deliveries is approximately 7 percent. The Project aims to identify women early in pregnancy, not only encouraging and assisting them in utilizing already existing prenatal care and social services, but also addressing such issues as smoking, drinking, weight gain, use of prescribed and non-prescribed drugs, and recognition of early signs of premature labor. Support for the project comes from private foundations and the District of Columbia, as well as the National Institute of Child Health and Human Development.

In addition, the Institute's Office of Research Reporting is actively involved in the Department's Healthy Mothers/Healthy Babies (HM/HB) program. The Institute printed a poster and take-home cards on the importance of prenatal care that were distributed to some 10,000 clinics which serve low income pregnant women. This poster and take-home cards are part of a series of posters and take-home

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cards emphasizing the importance of good nutrition and health habits during pregnancy sponsored by the Healthy Mothers/Healthy Babies program.

The Institute is also involved in a new effort with the HM/HB program to make educational materials such as pamphlets, prenatal calendars and other materials available to selected states who lack the resources to develop such materials on their own. These materials emphasize the importance of prenatal care, the need to avoid alcohol and cigarette usage during pregnancy, and the importance of a good, well-balanced diet while pregnant.

Question: In certain sections of Hartford, Connecticut, the infant mortality rate is 29.5 deaths per thousand compared to 11.4 for the entire State of Connecticut. How has your Institute addressed the specific problems of the inner city, and is there any hope that this dramatic difference can be changed?

Answer: In addition to the Better Babies Project which addresses problems of the inner city, the NICHD is also involved in another project, the District of Columbia Perinatal Study. This study was designed to identify factors associated with the birth of a low birth weight infant to resident mothers in the District of Columbia. The goal of the study is to identify risk factors which may be predictive of low birth weight deliveries, and also to identify, where possible, appropriate intervention strategies. Some of the factors that are being investigated include socioeconomic status, past pregnancy history, stress, use of prescribed and non-prescribed drugs, infection during pregnancy, smoking, and drinking. This project is viewed as an initial phase of an effort toward better assessment of the maternal and child health needs of inner city residents.

PERINATAL CENTERS

Question: A year ago the Director of NICHD proposed to develop two centers with emphasis on perinatal events, one on control of fetal growth and intrauterine growth retardation and the other a perinatal pharmacology and toxicology center. Were these centers actually established, and if so, where and at what funding level?

Answer: We expect to fund the intrauterine growth retardation center in FY 1985 at approximately $700,000. The location of this center will be determined in September.

At the level of the revised FY 1985 budget we will not fund the proposed perinatal pharmacology and toxicology center. No additional centers are planned in 1986.

MATERNAL AND FETAL MEDICINE RESEARCH

Question: I understand that there are two networks on maternal fetal medicine and neonatal intensive care. What do these networks do and why are both needed?

Answer: The NICHD has issued two requests for applications for cooperating multicenter networks, one for Maternal-Fetal Medicine Units (MFMU) and the second for Neonatal Intensive Care Units

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(NICU). The receipt date for applications is June 14, 1985. Once established each network will consist of 6 to 8 clinical centers working closely with NICHD scientific staff. Both networks will address different clinical problems in different patient populations. The MFMU network will investigate problems in clinical obstetrics, particularly those related to prevention of low birth weight. The NICU network will study the safety and efficacy of new treatment and management strategies that may be employed in the care of infants admitted to these units.

Question: What kind of clinical studies will they perform, and what will these studies lead to?

Answer: The principal investigators of the units, in cooperation with the Institute staff, will identify research topics of high priority and design protocols appropriate to the evaluation of optimum management in these areas. In the MFMU network, studies will address problems in clinical obstetrics, particularly those related to prevention of low birth weight such as managing and preventing premature labor or preventing intrauterine growth retardation. In the NICU network, they will investigate the safety and efficacy of new treatment and management strategies that may be employed in the care of sick newborn infants. The cooperative nature of this approach will allow the study of significant clinical problems occurring too infrequently for any one institution to have adequate numbers for a valid clinical study within a reasonable time span. These studies should provide information that will lead to a reduced incidence of low birth weight and improved intact survival of premature infants.

MENTAL RETARDATION

Question: What recent accomplishments can you tell us about in relationship to overall prevention of mental retardation?

Answer: Mandatory or voluntary screening programs for inborn metabolic disorders are in place in all 50 states and the District of Columbia. Early detection of these disorders through screening followed by the prompt initiation of appropriate therapy can prevent mental retardation consequent to these disorders including phenylketonuria (PKU), congenital hypothyroidism, and galactosemia.

The screening and treatment programs for phenylketonuria have resulted in a generation of young women with PKU who, under the treatment program, have reached child bearing age as essentially normal persons with full reproductive capacity. Infants born to these women are, however, most likely to exhibit brain damage and mental retardation. The only potential preventive measure at present is to have the mother's diet carefully managed throughout her pregnancy. The NICHD is conducting a clinical trial covering all 50 states designed to better understand the dietary management of these hyperphenylalaninemic women during their pregnancy with the aim of helping them to bear normal babies.

A serious health problem for American children comes from exposure to lead. It has been estimated that as many as 600,000

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children under age 6 show evidence of undue lead absorption. Children who have had lead poisoning and recover are frequently left with profound developmental impairments including mental retardation. Research is now drawing attention to the developmental effects of blood lead levels previously assumed to be subtoxic. National efforts to reduce environmental lead level are well under way and should aid in preventing mental retardation due to this environmental agent.

The fetal alcohol syndrome (FAS) has been established as a leading cause of mental retardation. It is a pattern of malformations found in nearly half of the offspring of severely and chronically alcoholic women who consume alcohol throughout pregnancy. Research is under way to determine the mechanisms by which alcohol exerts its toxic effect, and to determine the relation of FAS to alcohol ingestion during different periods of pregnancy and the amount of alcohol ingested. Prevention of mental retardation from this cause can be assured by abstinence from alcohol during pregnancy.

Mental retardation of a mild degree accounts for the vast majority of retarded persons and its prevalence is heavily associated with early child development under family conditions characterized by socioeconomic deprivation. Research has shown that intensive early educational and psychological interventions for biologically normal children at environmental high risk and their families can prevent the decline in cognitive performance common to socially disadvantaged children during the preschool years. Low birth weight babies are born more frequently to socioeconomically disadvantaged mothers. Recent follow-up studies of the graduates of modern neonatal intensive care nurseries show that low birth weight babies from socioeconomically deprived families are particularly vulnerable to later cognitive impairment. A national collaborative study, funded primarily by the Robert Wood Johnson Foundation, with partial support from NICHD, is currently under way to test the efficacy of combining early childhood educational and intervention services with pediatric care in reducing the incidence of health and developmental problems among these low birth weight infants.

FETAL RESEARCH

Question: In last year's NIH reauthorization debate, the absolute prohibition on fetal research became the one single factor that prevented the Senate bill from reaching the floor. What is fetal research and can it be as unacceptable as we heard during the discussions?

Answer: Fetal research involves research conducted during pregnancy that is directed toward the fetus rather than the pregnant woman. The studies may involve evaluations of fetal growth or well-being, assessment of fetal maturity, or studies directed toward improving the health status of the fetus or the outcome of pregnancy. Some research is therapeutic for the fetus and may involve some risk. Such research is permitted only if the potential benefits are judged to outweigh the risks. Some is not therapeutic, in which case it is permitted only if there is no risk or only minimal risk. Fetal research is necessary to improve pregnancy

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outcome in a number of conditions. Under Departmental regulations in effect since 1975, there have been no substantiated allegations of unacceptable fetal research supported by the Department.

Question: How important is fetal research in uncovering the causes of congenital defects and early childhood diseases?

Answer: Fetal research is essential if scientists are to be able not only to determine the causes of congenital defects and early childhood diseases, but also to develop means to diagnose, treat, or prevent these conditions. There is no other way to achieve these goals.

Question: Can you give us a few examples of the realities of fetal research that have had large health benefits for our children.

Answer: The story of Rh disease is a dramatic example of the importance of fetal research. This disease was shown to be caused by blood group incompatibility between an Rh-negative mother and Rh-positive fetus, resulting in destruction of the fetus's red blood cells and leading either to fetal death or to severe jaundice of the newborn infant. Fetal research made possible first the use of amniocentesis to determine how severely affected the fetus was by the disease so that intervention could be planned; second, intrauterine blood transfusion of the fetus to counteract the red blood cell destruction; and third, the development of Rh-immune globulin, Rhogam vaccine, to be given to the mother after delivery to prevent the condition in future pregnancies. A major cause of fetal and neonatal death or deafness, mental retardation, and cerebral palsy has almost disappeared as a consequence of this fetal research.

Another example is the prevention of respiratory distress syndrome (RDS), a major killer of newborn infants. Fetal research, again involving amniocentesis, led to development of a test, "L/S ratio", that indicated whether the lungs of the fetus were sufficiently mature that RDS would not develop if the fetus were delivered. This test had two benefits. First, it allowed physicians to choose the correct time for elective cesarean section delivery to avoid delivering a baby that would develop RDS. Second, women in premature labor, it allowed physicians to decide whether to try to stop labor because the lungs of the fetus were not yet mature. Further fetal research led to the development of more effective ways to stop labor, and of ways to induce fetal lung maturity within 24 hours by administering steroids to the mother, thereby allowing delivery of a baby who would not develop RDS. As a result of this fetal research the incidence of RDS and its associated mortality have decreased significantly.

Question: Are the Human research regulations and controls adequate to protect the fetus from inappropriate research?

Answer: The position of the Department, as stated by Secretary Heckler, is that our regulations provide necessary and appropriate safeguards for the conduct of fetal research. To reiterate, the Department's regulations for fetal research have been in effect

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since 1975 and there have been no improprieties in federally supported tal research.

Question: Please review the steps an investigator must take to receive approval for research on a human fetus.

Answer: Section 474(a) of the Public Health Service Act (P.L. 93-348), as implemented by DHES' regulation 45 CFR 46, requires basic protection for all human subjects involved in grant or contract-supported research activities. While the institution that receives, or is accountable for, the funds has primary responsibility for safeguarding the rights and welfare of all individual human subjects involved in research activities covered by the DHHS regulations, four different bodies or individuals must review and recommend approval before research involving a fetus can be granted. At each of these levels of review the application can be barred from funding if found to lack adequate protection for the fetus.

1. Institutional Review Board (IRB) - Each entity which applies for a grant or contract which involves biomedical or behavioral research on human subjects must establish an Institutional Review Board which must review and recommend approval of any application for funding. Each IRB must have at least one nonscientific community member, and must submit, with the funding application, a Protection of Human Subjects Assurance form (HHS Form 596).

2. NIH Study Section Initial Review - Before an application is referred to a Study Section, NIH staff must review the application and the Protection of Human Subjects Assurance form submitted with it. The Study Sections must review each application submitted to them for adequate protection to human subjects to be involved in the research.

3. National Advisory Council Review - All applications approved by Study Sections must be reviewed by the appropriate NIH National Advisory Council. As with all review bodies, National Advisory Councils are responsible for review of the protection of human subjects in each application.

4. Institute Staff and Director Review - Applications recommended for approval by a National Advisory Council must then be reviewed for human subjects protection and recommended for approval by the appropriate Institute staff and Director.

   In certain unusual situations, if the research is felt to be important but cannot meet one of the extremely restrictive fetal research regulations, the application requires a fetal research waiver. It is then submitted to the DHHS Secretary with a request that the DHHS Ethics Advisory Board (EAB) review it. The Secretary may submit it to the EAB for review, or choose to bar funding by not referring the application to the EAB.

5. DHHS Ethical Advisory Board (EAB) - The EAB, established by the Secretary, shall advise him or her as to ethical issues raised by applications for research involving the fetus. In accordance

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with Departmental regulations, the EAB uses special strict review criteria to assess the risks and benefits of the proposed research, and to determine if the research is the only means of obtaining the benefit(s). All meetings of the EAB are held in public, and the EAB must obtain appropriate public comment on the proposed research by such means as holding public hearings and/or requesting public comment. After its review, the EAB advises the Secretary on its findings.

6. DHHS Secretary - With the approval of the Ethical Advisory Board, the Secretary may waive specific requirements of the DHHS human subject protection regulations. In making such decisions, the Secretary will consider whether the risks to the subject are so outweighed by the sum of the benefit to the subject and the importance of the knowledge to be gained as to warrant the waiver, and that such benefits cannot be gained except through a waiver. All waivers will be published as public notices in the Federal Register.

PREVENTIVE RESEARCH

Question: In a speech before the American Pharmaceutical Association Dr. Wyngaarden said that 28 percent of NIH funds are directed to Preventive Research. What types of preventive research are being done by your Institute?

Answer: The NICHD has an especially important program in the area of prevention. Many health problems that afflict adults originate before birth or in childhood. Thus, the early stages of life offer exceptional opportunity to prevent diseases, disorders, and problems related to lifestyle. This concept underlies the mission of the NICHD: to develop new knowledge on early opportunities to prevent disease and disability, to ensure for all children the opportunity for a healthful and productive adulthood. Research on prevention is conducted in the following areas:

- Prevention of death and disability associated with high-risk pregnancies
- Causes and prevention of prematurity and low birth weight
- Metabolic, genetic, nutritional, and immunologic antecedents to disease and disability
- Effects of smoking, over-the-counter drug use, and other environmental substances on fetal development
- Causes, prevention, and amelioration of mental retardation
- Causes, prevention, and amelioration of birth defects
- Research on new and improved contraceptives and on contraceptive safety
- Determinants and consequences of adolescent childbearing
- Prevention of reproductive disorders

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In 1985 and 1986, increased emphasis will be placed on childhood injury prevention. Two special solicitations for grant proposals relating to injury prevention have been prepared. One focuses on studies of risk-taking behaviors, antecedents of injury, and behavioral interventions to prevent injury. The second, in the NICHD Small Business Innovative Research solicitation, will enlist the creativity of small business in America to develop devices that will reduce childhood injury.

Question: What percent of your budget is directed to preventive research?

Answer: Approximately 40 percent of the Institute's budget is devoted to prevention research. In FY 1984 this amounted to $106,514,000.

Question: How are the results of this research being translated into useful public information?

Answer: The results of the research are translated and transmitted to the public in a number of different forms. The Office of Research Reporting of the Institute has prepared numerous brochures for the lay public that constitute a "Facts About" series. Publication titles include Down Syndrome, Anorexia Nervosa, Cesarean Childbirth, Dysmenorrhea and Premenstrual Syndrome, Oral Contraceptives, Precocious Puberty, Pregnancy and Smoking, and Premature Birth. The Office of Planning and Evaluation of the Institute has coordinated consensus conferences and state-of-the-science conferences to examine the safety and efficacy of various medical procedures and explore the clinical implications of issues in medicine. Topics in this area include: Antenatal Diagnosis, Cesarean Childbirth, the Use of Diagnostic Ultrasound Imaging in Pregnancy, and Prenatal and Perinatal Factors Associated with Brain Disorders.

CLINICAL TRIALS

Question: In FY 1985 we provided your Institute with funding for five clinical trials. Have they been started?

Answer: The 5 trials for which funds were appropriated will not be ready to start in FY 1985. These clinical trials have been delayed for reasons which include cancellation of contractor's liability insurance and pending FDA approval for a new drug. In addition, two of the trials will now be funded as research grants, but the grant application deadline and review process will result in FY 1986 funding for these trials. However, NICHD will fund instead the following new clinical trials in FY 1985.

MAJOR NEW CLINICAL TRIALS IN FY 1985

The Effect of Parent Weight on Obese Young Children

The Treatment of Obesity in Children and Adolescents

Calcium and Phosphorus Nutrition in High Risk Infants

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Parenteral Amino Acid Requirements in Low Birth Weight Infants

Prevention of Otitis Media in Infants

Clinical Studies on Male and Female Fertility Regulation with LHRH Analogs

Clinical Studies with Capronor Implantable Contraceptive Drug Delivery System

Clinical Trial of New Drug Therapy in Treatment of Nephropathic Cystinosis

Treatment of Precocious Puberty with LHRH Analog

Treatment of Infertility with Gonadotropin Releasing Hormone

Effects of Growth Hormone Therapy on Children with Extreme Short Stature

Question: How many clinical trials will be supported in FY 1986?

Answer: It is anticipated that 33 clinical trials will be ongoing in FY 1986. In addition to the new trials begun in FY 1985, they are as follows:

Cooperative Multi-Center Neonatal Intensive Care Unit Network

Cooperative Multi-Center Maternal-Fetal Medicine Unit Network

Efficacy of Routine Ultrasound Screening in Pregnancy

Biological Predictors of Low Birth Weight

Prevention of Cytomegalovirus (CMV) Disease

Effects of Maternal PKU on Pregnancy Outcome

Prematurity and Gestational Genitourinary Infections

Intervention to Reduce Smoking During Pregnancy

Effects of Tonsil-Adenoid Surgery on Throat Infection

Urea Cycle Enzymopathies

Cell-Mediated Immunity in Congenital CMV Infections

Teen Social Behavior and the Prevention of Smoking

ECMO in Newborn Respiratory Failure

Strict Control of Diabetes in Pregnancy

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Use-Effectiveness Study of Cervical Caps

Clinical Studies on Human Milk

Spermicides and Sexually Transmitted Diseases

Phase II Clinical Studies with LHRH Agonists

Human Biochemical Genetics

Growth Hormone Releasing Factors

Physiology of Puberty

Mechanism of Pubertal Growth

Question: Do you have any clinical trials waiting to be started?

Answer: The following clinical trials could be started in FY 1986, if additional funds were available:

1. Effectiveness of Physical Therapy for Infants at Risk for Developmental Disabilities and Mental Retardation

2. Clinical Studies with a New Diaphragm

3. Clinical Studies with a Long-Acting Spermicidal Formulation

4. Clinical Studies with a Long-Acting Testosterone Ester

5. Effects of Growth Hormone Releasing Factors

6. Studies on New Long-Acting Injectable Progestins

Question: How much funding will they require?

Answer: An additional $1,450,000 would be required to fund these clinical trials.

BUDGET RESTRAINT vs. RESEARCH

Question: Your budget request for FY 1986 is $20 million less than appropriated in FY 1985. What are the areas of research that you have to curtail?

Answer: In terms of budget authority, the FY 1986 request for NICHD is approximately $20 million less than the FY 1985 appropriation. However, from a program level perspective, taking into consideration the funds to support research grants and a center in FY 1986 which were obligated in FY 1985, the FY 1986 budget represents a 1.5 percent increase over the FY 1985 comparable level. The FY 1986 request will allow the NICHD to continue progress in all areas.

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Question: What current programs are being cut back or frozen?

Answer: We do not anticipate that we shall have to cut back or freeze any specific programs.

Question: Are there any new exciting areas of research that are not being pursued?

Answer: There are several research areas which will not be pursued in FY 1986. Examples include:

a) The development of new bacterial vaccines, for example, haemophilus influenza, meningococcus, and typhoid.

b) The use of the mouse as a model for the development of "gene therapy." We have successfully introduced new genes into fertilized mouse eggs, implanted the eggs in surrogate mothers, and produced viable progeny that stably express the new genetic trait. Much of the fundamental research has been accomplished here already, and our ability to identify applications for this model would be delayed.

c) Futher development and use of innovative software programs which will permit patients with chronic illnesses to participate effectively in their own treatment through the use of a home computer.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: As with all labor-intensive functions, the major costs of the function are related to the number of labor hours required by the process. Therefore, efficiencies in the process which serve to lower the number of labor hours provide the greatest promise for cutting costs.

Use of advanced office technologies are being considered and implemented to decrease the bulk of paper transmitted and stored. Examples include the electronic transfer of award statements and review documents, microfilm recording and storage of unfunded projects, and increased use of word-processing technology to include optical character readers so that incoming material may be stored, manipulated or reproduced without requiring retyping.

Since the amount of time required for substantive scientific review and evaluation is not amenable to reduction, cost savings here apply to obtaining the lowest transportation costs available for reviewers through use of special "government" airfares, centralizing review meetings to decrease distances traveled, and organizing meetings well to assure accomplishing review in the least amount of group time possible. Although it has not yet proved practicable, the use of teleconferencing is an option for future application which is available.

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Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: The NICHD has no formally organized program specifically directed toward this function. However, all Institute managers are charged with the responsibility to address the problem of handling all processes more efficiently and effectively. The Institute is active in NIH-wide committees and groups whose function is to coordinate and consolidate uniform operations among Institutes. These groups are quite effective for information exchange and development of new ideas.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: The Institute's Office of Grants and Contracts has participated directly with the NIH Division of Research Grants in implementing modernization of the grants awards process and is continuing to study ways in which receipt and review of grant proposals can be improved. The automated awards process has eliminated paper transfers between buildings and reduces by 4 to 7 days the accurate and complete processing of the award and its related fiscal accounting.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: We address this issue, first, by constantly emphasizing the principle that strong, scientific peer review is the very essence of the process for review and funding of research proposals. Toward this goal, we strive to maintain rosters of review group members who are tops in science and who provide appropriate representation of the many scientific disciplines that contribute to pursuit of our mission. We support the review groups in part by regularly updating review guidelines to accommodate changes in scientific technology, NICHD program initiatives, and research institutions' way of conducting research, and publicizing these guidelines in the research community. A more recent innovation in the peer review process has been to send the review critique to the applicant for funds, and to establish a formal procedure by which the applicant's institution might appeal a rating that the applicant feels is unjustifiably low.

ORAL CONTRACEPTIVES

Question: I understand that sales of oral contraceptives are up due in part to the introduction of the new tri-phasic forms. Do you plan to conduct studies to evaluate their safety and efficacy?

Answer: Yes. The NICHD plans to launch a comparative clinical study of oral contraceptive users. Women undertaking conventional, biphasic, and triphasic oral contraception will be followed for a period of one year. The goal of the study will be to compare the average changes in cholesterol, blood pressure, glucose tolerance, and coagulation parameters. It is hoped that this comparative study

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will show that the metabolic changes in phasic oral contraceptive users are as small as those in today's users of low-dose conventional oral contraceptives. The number of contraceptive failures will also be counted, although this number is expected to be exceedingly small.

SUDDEN INFANT DEATH SYNDROME

Question: Is there any medical evidence that links vaccinations for diphtheria, pertussis, and tetanus (DPT), with subsequent death ruled as sudden infant death syndrome?

Answer: The NICHD Cooperative Epidemiological Study of Sudden Infant Death Syndrome (SIDS) Risk Factors analyzed the immunization status of 716 SIDS cases and a control group matched for age, race, and birth weight. The results do not suggest an association between DPT vaccination and sudden infant death.

RESEARCH ON CONTRACEPTION

Question: An FDA-appointed Public Board of Inquiry recommended in late 1984 that the Government reject a request for approval of the injectable contraceptive Depo-Provera. Has the NICHD been involved in research on injectable contraceptives?

Answer: Yes. The NICHD has for a number of years been supporting research on the development of drugs other than Depo-Provera. We have done extensive research on the injectable drug called "norethindrone enanthate." However, the FDA has not given us permission to initiate large clinical trials with it. In collaboration with the World Health Organization, we have developed a new generation of injectables that appear to have more desirable characteristics. Clinical studies with these new drugs should commence within a year.

Question: Do you agree with the recommendation to reject its (Depo-Provera) use in the United States?

Answer: The initial inquiry concerned primarily the effects of Depo-Provera (DMPA) on the occurrence of breast cancer. A large body of data from women using DMPA around the world has been collected over the last few years and it would seem premature to reject DMPA on the basis of breast cancer risk until these data have been analyzed. Additional data concerning DMPA and the risk of other reproductive system cancers will be analyzed concurrently with the breast cancer data. Determining the nature of the association between DMPA and cancer is a very complex area of research. Very careful analysis of the data should be made before setting a final disposition for DMPA approval in this country.

Question: What is the status of the studies involving the contraceptive cervical cap?

Answer: Clinical trials supported by NICHD are currently under way comparing the safety and efficacy of the cervical cap with the vaginal diaphragm. Preliminary data indicate that the cap may be somewhat less effective than the diaphragm. There is also some concern expressed about the effect of the cap and the spermicide

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contained in it on the cells covering the cervix. This study should be completed in another year and the data will be submitted to the FDA for their assessment.

Question: What do we know about the association, if any, between the use of spermicidal gels, in conjunction with barrier methods of contraception, and subsequent birth defects?

Answer: The overwhelming evidence from the population literature now suggests that there is no relationship between use of spermicides and the occurrence of subsequent birth defects.

EXERCISE IN PREGNANCY

Question: Is there any evidence that fetal risk is increased if a physically active woman adopts a more sedentary lifestyle during her pregnancy?

Answer: In general, any individual who reduces his or her level of regular physical activity will become less well "conditioned." Research on the effects of exercise during pregnancy has tended to focus on the risks of continued, or even increased, there is no perceived increased risk in decreased physical activity during pregnancy, although obstetrical recommendations favor invigorating, pleasant exercise for both physical and mental well-being. Either extreme of physical activity that may be occasioned by sportive or occupational demands is of potential concern and deserves more attention in both research and clinical recommendations.

Questions Submitted by Senator Daniel K. Inouye

ACCIDENT PREVENTION

Question: The Committee is pleased with the extent to which NICHD has targeted efforts focused upon the developmental aspects of accident prevention. The Committee would appreciate learning of the Institute's future plans in this particular area.

Answer: Recognizing that unintentional injuries (accidents) are the leading cause of death and disability among children and young adults in the U.S., the Human Learning and Behavior (HLB) Branch of the NICHD has recently issued a Request for Applications (RFA), entitled "Injury and Injury Prevention in Children", with July 15 as the deadline for receipt of applications. Because childhood injuries are perceived as having a significant behavioral component, the Institute's initiative is designed to develop behavioral intervention strategies that can impact upon this important public health problem. In addition, the Institute has also stimulated interest in childhood injury among researchers in the private sector. In its April 15 solicitation of the PHS Small Business Innovative Research (SBIR) program, NICHD is encouraging small business firms to develop procedures and devices to reduce childhood injury.

CHRONICALLY-ILL CHILDREN AND THEIR FAMILIES

Question: The Committee would also appreciate learning of proposed follow-up plans for the recommendations raised at the

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Vanderbilt University Symposium entitled "Public Policy Affecting Chronically Ill Children and Their Families."

Answer: The Vanderbilt University Symposium entitled "Public Policy Affecting Chronically Ill Children and Their Families" makes 10 recommendations. These recommendations with the NICHD response to them are given below.

Recommendation: Support for basic biomedical research, via the mechanisms of the NIH, should remain a very high priority.

Response: The research programs of the NIH give primary emphasis to the production of new knowledge through basic research. This emphasis will continue accompanied by vigorous efforts to move emerging new knowledge promptly into treatment and service applications.

Recommendation: The investment in basic biomedical research should be balanced with an equally vigorous commitment to basic research in other critical areas, including behavioral sciences and health services research.

Response: The NICHD currently supports a balanced program of biomedical, biobehavioral, and behavioral research in its Center for Research for Mothers and Children which holds primary responsibility for research on handicapped children and their families.

Recommendation: A number of areas appear especially promising, for example, in primary prevention of handicapping conditions and in improving the process of childhood coping with chronic illness. Support for basic research in genetics, in the development of certain new technologies (such as the insulin pump for diabetes), in epidemiology, and in family coping and adjustment merit special attention.

Response: The NICHD currently supports a major program project concerned with the study of handicapped individuals living and working in natural settings. In recent years, several states have moved to establish record systems serving to guide their service delivery to mentally retarded and developmentally disabled persons. These records have emerged as potentially valuable data bases, particularly in California and New York, which can provide data bearing on the health, adjustment, and development of individuals with mental retardation or developmental disabilities. The NICHD staff has encouraged programming efforts to develop projects which exploit these potential resources.

Recommendation: Given the relative infrequency of many chronic childhood illnesses, adequate numbers of children with any specific disease may not be found in a single center. Interinstitutional research should be fostered and supported.

Response: The NICHD supports a significant amount of inter-institutional research through both the research grant and contract mechanism and routinely endeavors to include collaborative interinstitutional research in its programming. It has supported the National Collaborative Phenylketonuria (PKU) program and

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currently supports the cooperative efforts of the 14 clinics forming the interinstitutional study of diet discontinuation for children with PKU. The contract mechanism is employed for the cytogenetic registry which provides a uniform procedure for collecting and reporting interinstitutional cytogenetic information for inclusion in a central registry.

Recommendation: Successful collaboration among different biomedical disciplines should be expanded to stimulate joint research ventures among such disciplines as psychology and medicine, physiology and nutritional sciences, nurse-researchers and pediatrics.

Response: Interdisciplinary collaborative research is well established in research programs supported by the Institute. The Mental Retardation Research Centers Program, administered by the Institute, fosters interdisciplinary research as one of its major objectives. The Institute has recently issued a program announcement calling attention to its interest in funding meritorious research training programs emphasizing training in interdisciplinary research.

Recommendation: Support for the training of scientists, especially from the clinical disciplines, to develop strong quantitative and data management skills and incorporate the tremendous expanding knowledge in the field of clinical epidemiology, needs expansion.

Response: Existing NIH research training award mechanisms are adequate to provide for the recommended expansion. These include, among others, National Research Service Awards for Senior Fellows, Individual Postdoctoral Awards, Modified Research Career Development Awards, Clinical Investigator Awards, and Institutional Training Grant Awards. Directed research supported by the Institute also provides a base for training and for enlisting the interest of new investigators in the field. The new physician scientist award is also beginning to attract physicians to research training.

Recommendation: Much basic research in child development has come recently from the area of developmental disabilities, often with support from the National Institute of Child Health and Human Development. The skills and developmental knowledge arising from this research have major implications for chronic illnesses in childhood as well and should be creatively applied to this area.

Response: The Institute participates actively in moving emerging new knowledge from basic research into services for chronically ill children. This is accomplished through support of conferences and workshops, staff participation in interagency consideration of issues, and in the fostering of clinical and field trials for new developments.

Recommendation: Recent efforts to clarify the ethical considerations in research on children are commendable and outline an area of fruitful future investigation. Though the balance between ethical pursuits of new knowledge and preservation of the rights of children may be difficult to achieve, inattention to the

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problem may lead to potentially dangerous and unproven therapies applied haphazardly to children.

Response: The NIH maintains and implements a strong program for the protection of human subjects from research risks. The rights of children to protection, particularly those who are handicapped, resident in child care institutions, and lacking competence to effect sound personal judgements, are protected under the NIH system. Through the peer review process, continuing vigilance is exercised to insure that all research grant applications and contract proposals are reviewed with due consideration given to the protection of human subjects and for the moral and ethical aspects of the research proposed. The standards and guidelines set for the protection of human subjects have been developed with the full participation of the scientific community and, while they do set some strictures limiting the freedom of research, they achieve a reasonable balance between research needs and the national ethic governing protections for the rights of children. The hazards of potentially dangerous and unproven therapies arise in the context of practice rather than research; research to demonstrate their safety and efficacy, or lack thereof, is the best solution to this problem. The NICHD will, on April 16-18, 1985, cosponsor a conference with Vanderbilt University on the ethical aspects of research with the severely handicapped.

Recommendation: The benefits of research should find timely application in service programs for children and families. The development of regional, integrated programs for chronically ill children will improve the daily interaction between those doing basic research and those providing varied levels of service.

Response: In large measure, the need for development of regional, integrated programs which move new research knowledge into services for chronically ill children has guided the NICHD in its admininistration of the Mental Retardation Research Centers Program and its relationship to the University Affiliated Programs (UAP), administered by the Administration on Developmental Disabilities (ADD). Ten of the twelve MRRCs were constructed to foster a close relationship with UAPs and have continued to operate as functionally and administratively linked resources joining MRRC research to UAP service and service training. Not all UAPs were developed with construction grant awards and today more than 50 UAPs are in operation. They provide a network of service and service training resources with a distinctive regional character. Joint meetings of the Directors of MRRCs and UAPs are held annually to promote information dissemination.

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SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will stand in recess until tomorrow morning at 9:30 a.m., in room SR–428A, the Small Business Committee hearing room over in the Russell Building. At that time we will conclude our hearings on the National Institutes of Health with testimony from the directors of the following institutes: the National Eye Institute; the National Institute of Environmental Health Sciences; the National Institute on Aging; the Division of Research and Resources; the John Fogarty Center; the National Library of Medicine; and the Office of the Director of Buildings and Facilities.

I thank you very much, and we will see you all tomorrow.

[Whereupon, at 10:17 a.m., Wednesday, March 20, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 21.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

THURSDAY, MARCH 21, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:37 a.m., in room SR-428A, Russell Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Proxmire, and Chiles.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

NATIONAL INSTITUTES OF HEALTH

NATIONAL EYE INSTITUTE

STATEMENT OF DR. CARL KUPFER, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH
EDWARD McMANUS, DEPUTY DIRECTOR, NATIONAL EYE INSTITUTE
DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

OPENING REMARKS

Senator WEICKER. The committee will come to order.

We will hear first from Dr. Carl Kupfer, Director of the National Eye Institute as to the fiscal year 1986 budget, $164 million, which is $17 million less than appropriated in fiscal year 1985. I might add, we welcome Senator Andrews. He has had his own appropriations hearings going on simultaneously with those of this subcommittee. I know, indeed, his hearing picks up again at 10 o'clock. If there is anything he would like to do at this juncture, I will be glad to defer to him.

Senator ANDREWS. Senator, I appreciate that. Let me say to you and to Senator Proxmire, my deep regrets for not being able to be here more often. We have been staffing it. We have been following the progression of the hearings, and I want to commend you, Mr. Chairman, for your efforts to preserve NIH and biomedical research. For the last

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10 days. I have been sitting almost imprisoned in the Senate Budget Committee looking at the various cuts they made, and I guess I am a betting man. Gosh, you can't be a farmer without being a betting man, and if I were going to bet, I would bet there are not five U.S. Senators that will support the David Stockman cuts at NIH. The research to fight cancer, and find answers to heart disease, stroke, all the rest, those are not spending programs; those are investment programs, and the work this subcommittee does is extremely important for the future of this country.

I also want to commend Dr. Wyngaarden for the job he is doing because taking over this group is no small challenge, and he certainly has proven effective as the Director of NIH.

Let me also point out my total support of our chairman's efforts to save the 6,500 grants for 1985. As you know, in fact the Washington Post even found out about it, there is a letter from the Comptroller General stating that the administration's proposal was not only foolishness, but illegal. That is refreshing for one of us who signed on to the resolution several weeks ago with the chairman of the full committee, the chairman of the subcommittee and a number of the rest of us, who believed the administration was, indeed, in fact in error.

Mr. Chairman, I wanted to take this time today, even though I have an Agriculture Subcommittee hearing going on right now on a very important bill. They are talking about dairy and some of those other things.

Senator PROXMIRE. I'll go with you. [Laughter.]

Senator ANDREWS. We have even recruited Lowell to vote for farm credit programs, if you noticed. You kind of dropped off the bandwagon and Lowell filled in for dairy farmers. We appreciate it a lot. I have to go over and do my transportation one. I wanted to tell the chairman, and I am sure you know also, Senator Proxmire, my total support for what we are doing in this subcommittee and the fact it is extremely important to the future of our country, and my apologies to you for not being here more often. I support you all the way, and we hope we can put as good a bill together as we did last year.

Senator WEICKER. Thank you, Senator Andrews. I am delighted to go ahead and support the farmers. I never realized how much a cow looked like an Amtrak train. [Laughter.]

Senator ANDREWS. It's amazing what happens when you become the chairman of the Senate Transportation Subcommittee. [Laughter.]

Senator PROXMIRE. Whether it is a cow or Amtrak train, some Senators can milk either one of them. [Laughter.]

Senator ANDREWS. And you know the right end to work on. [Laughter.]

PREPARED STATEMENT

Senator WEICKER. All right, down to business.

Dr. Kupfer, you go ahead and proceed in any way you wish. We will insert your statement in the record first

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Dr. KUPFER. Thank you, sir.

I would just like to introduce the Deputy Director of the National Eye Institute, Mr. Edward McManus.

[The statement follows:]

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STATEMENT OF DR. CARL KUPFER

Eye disease and visual impairment impose enormous costs upon this Nation. Eleven million Americans are visually impaired, and half a million of these are legally blind. The cost of professional care and special services for people with eye problems is now $16 billion a year. To spare as many people as possible from the threat of visual disability, and lessen the burden it imposes on society as a whole, the National Eye Institute (NEI) supports research on the prevention, diagnosis, treatment, and rehabilitation of a wide range of vision disorders.

Development of more effective means to combat these disorders requires a greater understanding of the parts of the nervous system that are devoted to vision. For that reason, the NEI is supporting extensive research in a field that represents one of the last great frontiers of biology. I am speaking of neurobiology--the science that seeks to learn how nerve cells develop, perform their complex functions, and die. The NEI has a major investment in this field of research. In fact, among the Institutes of the National Institutes of Health, we are second in the amount of funds devoted to studies in neurobiology.

I would like to tell you about some of the fundamental questions we are attempting to answer through this research program. The biggest question is, simply, how do we see? How is light used by the eye and brain to form complex visual images? How does the brain integrate this information with other sensory input such as sound, and then initiate appropriate action? NEI-supported scientists are beginning to answer these questions through research that is helping to reveal what happens at each step along the pathway of visual nerve cells, from the retina of the eye to the higher visual centers in the cortex of the brain.

For example, biochemical studies are yielding increasingly detailed information about the workings of the retinal photoreceptors. These are the visual system's "front-line" nerve cells--the ones that absorb incoming light and use it to make signals that are passed on to other nerve cells for more sophisticated processing. Now we are obtaining large amounts of information about the biochemical changes that occur when these cells react to light. We expect that this research will eventually tell us how a healthy, functional photoreceptor differs from a diseased one, and add to our understanding of a wide range of blinding degenerative conditions affecting the retina.

Other fundamental studies in neurobiology may eventually lead to improved rehabilitation of people who have suffered damage to visual nerve cells. This research deals with the growth and regeneration of visual nerve tissues. For example, NEI-supported investigators studying animal models have obtained important new information on how growing nerve cells make specific connections with each other to form highly organized networks. Other studies involving transplanted nerve tissue have shown that under certain conditions a nerve transplant can at least partially connect itself to host nerve tissue. The ultimate goal of these studies is to discover a means of getting damaged nerve tissue to regenerate. This would be an enormous advance that might eventually permit the restoration of sight to many victims of eye disease and injury.

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In addition to the above, we know that in certain circumstances the brain itself can compensate for the loss of some of its nerve cells by having surviving cells take over the function of the ones that were destroyed. Investigators supported by the NEI are seeking to learn how this flexibility--or plasticity--is achieved in the developing visual system. The hope is that we may be able to encourage plasticity in situations where it would not naturally be expected, and thereby allow sight to continue in people who have suffered irreparable damage to some major group of visual nerve cells.

Molecular biology has also become a major contributor to progress in vision research. One particularly exciting use for the new techniques involves the enzyme aldose reductase. You may recall that I have mentioned this enzyme before. It is believed to contribute to eye and nerve damage in people with diabetes. The NEI is now directing a multicenter clinical trial to determine whether one of the newly developed drugs that inhibit the enzyme can prevent complications in people with insulin-dependent diabetes. But we must also explore the possibility of controlling aldose reductase by other means. Consequently we are supporting research to identify the genes that control the production of this enzyme. Once the molecular genetics of aldose reductase have been worked out, there will be a possibility of using gene therapy--rather than drugs--to suppress the enzyme's activity, and perhaps significantly reduce these complications.

Molecular biology is also being applied to the study of an important retinal protein called the S-antigen. NEI-supported investigators are close to cloning the gene for this protein, which is believed to play a role in many cases of uveitis, an eye disease that is responsible for 10 percent of all visual impairment in the United States. The protein will now be split apart and analyzed to determine which parts contribute to uveitis and which are essential for normal visual function. These studies may also lead to the development of gene therapy to prevent visual loss.

In addition, scientists at the NEI, Johns Hopkins, and the University of Wisconsin are working to clone the gene for an enzyme that is deficient in people with a blinding disease called gyrate atrophy. To date, gyrate atrophy is the only one of the hereditary retinal diseases known to be associated with an enzyme defect, and there is reason to hope that this research, too, may eventually lead to a specific gene therapy.

Within the past year, there also has been considerable progress in research on the biochemical basis of cataract, an eye disease that now necessitates more than 700,000 operations a year in this country. Scientists supported by the NEI are beginning to identify the steps by which oxygen within the eye is converted into "activated" forms that can damage the lens and contribute to the development of cataract. With this new information on the exact types of oxygen-containing molecules which are doing the damage, and on the sites where they are active within the eye, scientists will be in a far better position to design potential anti-cataract agents. Because a number of pharmaceutical companies are already working on this problem, it appears likely that the recent laboratory findings will be put to use as guides for drug development very soon.

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In addition to supporting a wide range of laboratory research, the NEI continues to place a high priority on clinical trials as a means of assessing therapeutic measures that cannot be fully evaluated in any other way. One example, which I mentioned earlier, is the recently initiated trial of aldose reductase inhibitors as preventives for the complications of diabetes. Another is the Branch Vein Occlusion Study, which yielded its initial results last year. It found that laser treatment can improve central vision in some patients who have experienced blockage of a retinal vein. This is an eye problem that affects many people who have high blood pressure or diabetes, and the current clinical trial is continuing to explore the risks and benefits of laser treatment in people with the disorder.

Among the new clinical trials that we plan to initiate this year are two which will explore new methods of improving the success rate of corneal transplant surgery. One study will evaluate a new immunosuppressant drug as a means of preventing rejection of corneal transplants, and the other will determine whether preoperative matching of donor and host tissue using HLA markers can be of value. Also, we plan to initiate a study comparing different methods of repositioning the retina during reattachment surgery, and another one to compare alternative treatments for ocular melanoma, a potentially fatal eye tumor.

I believe the research I have discussed today provides concrete evidence that the NEI seeks out and makes use of scientific opportunities to reduce the national burden of eye disease and disability. In so doing, we are not only bringing about the next wave of advances in vision care, but also generating basic knowledge that will have applications beyond the limits of the visual system.

Mr. Chairman, the 1986 budget request for this Institute is $164,396,000, a decrease of $13,930,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants funded. Specifically, in 1985 this Institute will fund 299 new and competing grants of which 38 will receive 3 years of support.

I will be happy to answer any questions.

Biography of Dr. Carl Kupfer

February 9, 1928. New York, New York.

Education: A.B., Yale University, 1945-48. M.D., The Johns Hopkins Medical School, 1952 Certified. American Board of Ophthalmology, 1958.

Professional History: Internship and Assistant Residency, Wilmer Eye Institute, Johns Hopkins Hospital, 1952-1954. Laboratory Assistant, Biostatistics, Johns Hopkins School of Medicine, 1953-58. Research Fellow in Ophthalmology, Wilmer Eye Institute, Johns Hopkins Hospital, 1957-58. Research Fellow in Ophthalmology,

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Harvard Medical School, 1958-60. Instructor in Ophthalmology, Harvard Medical School, 1960-62. Assistant Professor of Ophthalmology, Harvard Medical School, 1962-1966. Professor and Chairman in Ophthalmology, University of Washington School of Medicine; Research Affiliate, University of Washington Primate Center, 1966-70.

Professional Organizations: American Physiological Society, Association for Research in Vision and Ophthalmology, American Academy of Ophthalmology, American Ophthalmological Society, Pan American Ophthalmological Society

Honors and Awards: Editorial Board, Investigative Ophthalmology, 1969-1977. Editorial Board, American Journal of Ophthalmology, 1971 to present. Member, Scientific Advisory Committee, Fight for Sight, Inc., 1971 to present. The Secretary's Special Citation, Department of Health, Education, and Welfare, April 1972. The Superior Service Award, Department of Health, Education,and Welfare, May 1974. Ticho Memorial Lecture, September 1974. Migel Medal, American Foundation for the Blind, October 28, 1976. Public Service Award in Ophthalmology, American Academy of Ophthalmology and Otolaryngology, October 1977. Speaker, Glenn A. Fry Award Lecture, American Academy of Optometry, December 1981. Senior Executive Service Bonus, Department of Health and Human Services, 1981. Johns Hopkins Society of Scholars, Johns Hopkins University, May 1982. Honorary Doctor of Science Degree, Scheie Eye Institute, University of Pennsylvania, November 1982. Member, Institute of Medicine, January 1983 to present. Speaker, XIV Jules Stein Lecture, Los Angeles, California, April 1983. Recipient, Special Award of Honor, The Juvenile Diabetes Foundation, June 1983. Recipient, David Rumbough Memorial Scientific Award, The Juvenile Diabetes Foundation, June 1983. Recipient, Presidential Rank Award of Meritorious Executives, 1983. Lecture, New York Academy of Medicine, New York, N.Y., March 1984. Bowman Lecture, The Ophthalmological Society of the United Kingdom, London, England, April 1984. Recipient, The Lighthouse Pisart Vision Award, October 1984. Lecture, Howard University Hospital, Washington, D.C., December 1984. Member, Board of Trustees, Helen Keller International Inc., 1975 to present. Coordinator for USA, US-Japan Collaborative Agreement in Vision Research, 1976-1982. Organizer, Oxford Assembly, International Agency for the Prevention of Blindness, (IAPB) 1978. Coordinator for USA, Priority Area "Eye Diseases," US-USSR Program for Health Cooperation, 1978-1981. Speaker, General Assembly of the World Council for the Welfare of the Blind, Antwerp, August 1979. Director, WHO Collaborating Center for the Prevention of Blindness, National Eye Institute, Bethesda, MD, 1979. President, IAPB, 1982 to present.

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MAGNITUDE OF THE PROBLEM

Dr. KUPFER. Perhaps it might be appropriate to begin with some idea of the magnitude of the problem that we are confronted with. There are some 11 million Americans who are visually impaired and of those, 500,000 are legally blind. The cost of professional care and special services that are extended to these people with eye problems is about $16 billion per year. And, with the aging of the population that is taking place, we are going to see a doubling of these figures by the year 2000. Just to give you one example, the number of Americans with cataracts today probably amounts to about 5 million, and by the year 2000, that will double to 10 million. Obviously the economic and social impact of these figures are extremely impressive, indeed.

ACCOMPLISHMENTS OF DIABETES RESEARCH

I would like to briefly highlight some of the accomplishments and studies that are underway and focus primarily on our program in diabetes research. The National Eye Institute has the second largest diabetes research budget at NIH in terms of total dollars as well as the percentage of total budget invested in diabetes research, second only to NIADDK. We have previously reported the results of a clinical trial which demonstrated the success of treating advanced diabetic retinopathy with the laser. This treatment reduced the incidence of blindness by some 60 percent, and we have now calculated that since the year 1976 when these data became available, some 4,200 diabetics have been saved from blindness each year at a net annual savings of some $100 million.

At the present time, two other clinical trials are underway looking at different aspects of diabetic complications in the eye: the early treatment of diabetic retinopathy and the use of the operation vitrectomy for those patients no longer able to respond to laser treatment. We are also contemplating a new trial to try to treat one of the complications of early diabetes, the collection of fluid in the macula, which is the part of the retina, the seeing part of the eye, which has the highest potential for sharp central vision.

An area that we have discussed previously, and I would like to focus on today is the research that has been underway for a number of years in the intramural laboratories at the National Eye Institute on an enzyme called aldose reductase which appears to be involved in the initiation of a variety of diabetic complications. We have talked about this in the past, but I would like to again bring to your attention the fact that controlling the activity of this enzyme with inhibitors may be a very new and important approach to the treatment of diabetes, not only in terms of the complications in the eye but even more exciting, some of the complications in the nervous system diabetic neuropathy, and possibly even complications in the kidneys, which will often lead to the death of the diabetic patient.

We have underway a clinical trial to test one of the new inhibitors of this enzyme that was developed by Pfizer Pharmaceutical, and we are

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collaborating with this drug firm in this clinical trial. Patient recruitment should be finished by August, and we should have some results as to whether or not we can prevent not only the retinopathy but the diabetic neuropathy in juvenile diabetics when treatment is begun very early in the course of their disease.

The exciting thing about the use of inhibitors of this enzyme is that this is a novel approach to diabetes. It does not focus primarily on making insulin available; nor on reducing the blood sugar, but it is an entirely new approach which has the potential of blocking the complications of diabetes.

There are now many drugs that are being developed to inhibit this enzyme. There are 15 pharmaceutical houses that have been stimulated by the research done at the National Eye Institute to enter this field and develop new drugs to inhibit the enzyme, and we are going to see opportunities for testing these drugs very early on.

In addition, the new techniques of molecular biology enabled us to clone the gene that is responsible for producing this enzyme and, with that having been done, the opportunity of developing new methods that prevent the gene from turning on the enzyme is a distinct possibility.

So I think within the next few years, we are going to see a very exciting story unfold with reference to the complications of diabetes.

I would like to briefly mention that we have just successfully completed another clinical trial, the treatment of occlusion of the veins that drain the blood from the eye, from the retina. Next to diabetic retinopathy, this is the main cause of vascular disease in the retina, and we have been able to show that treatment with the laser not only brings about a restoration of vision faster than no treatment at all, but that the improvement of vision with laser treatment is significantly greater.

So in summary, we are very actively involved in both seeking basic knowledge in the laboratory, and as soon as that information is available, applying it to clinical problems. I will be happy to answer any questions, sir.

Senator WEICKER. Senator Proxmire.

RADIAL KERATOTOMY

Senator PROXMIRE. Dr. Kupfer, one subject you didn't mention in your prepared statement was radial keratotomy.

Dr. KUPFER. Yes, sir.

Senator PROXMIRE. That is the controversial technique of correcting nearsightedness with surgery—tiny slashes of the cornea—rather than glasses. I understand the Eye Institute is funding a 5-year study of the technique. Can you tell us how much the study will cost?

Dr. KUPFER. To date this study has cost about $3 million, sir. We estimate that the total cost will be about $5 million.

Senator PROXMIRE. Reports on the first year of the study have indicated those with mild myopia have better results from the surgery than others with extreme myopia.

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Dr. KUPFER. Yes, sir.

Senator PROXMIRE. So the procedure does not seem to treat a particularly serious condition. In fact, glasses or contact lenses would be a much cheaper alternative to the surgery. Are there any situations in which the surgery would be called for because corrective lenses can't be used?

Dr. KUPFER. Radial keratotomy, has been primarily performed on those individuals who for a variety of reasons either do not wish to wear spectacles or do not wish to wear contact lenses or cannot tolerate them, and as you correctly point out, it is primarily for those who have low levels of nearsightedness, low levels of myopia.

There are other operative procedures directed toward individuals with very high levels of myopia in which the use of spectacles or the use of contact lenses are not satisfactory. But for radial keratotomy, one would have to say that the motivation is to avoid wearing glasses or avoid wearing contact lenses.

Senator PROXMIRE. I understand the vast majority of ophthalmologists still question radial keratotomy's long-term effects since changes in vision have been known to occur 5 years or more after the surgery. There is always the risk of infection with surgery. Also, there is a slight loss of endothelial cells.

Leaving that aside, I am concerned over the Institute's decision to put millions of dollars into testing a surgical procedure that could sharply increase medical care expenses when the condition to be corrected is mild and can be handled with corrective lenses at one-tenth the cost of surgery. What factors entered into your decision to proceed with this study?

Dr. KUPFER. I think that is a very pertinent question, sir, and I am glad to address it. First of all, the operation was introduced into the United States approximately 7 or 8 years ago and caught the imagination of a number of individuals who wanted to do away with glasses and contact lenses and suddenly the ophthalmologic community was confronted with a procedure that had not been vigorously tested. As you rightly point out, it was an operation for a condition which ordinarily could be easily corrected with spectacles or contact lenses.

The ophthalmologic community itself felt that it was necessary to scientifically test both the safety and the efficacy of this procedure, and a group of ophthalmologists put together a research grant proposal which was submitted to the National Eye Institute. Our National Advisory Eye Council was very concerned that before such a procedure—which as you point out could add to the costs of eye care as well as perhaps produce certain complications in a condition which could be safely corrected otherwise—became extremely popular in the United States, a scientifically vigorous clinical trial should be conducted.

So with the interests of the ophthalmologic community, on the one hand, and the enthusiasm of the National Advisory Eye Council, on the other, we felt the most responsible thing we could do for the American public was to find out if this procedure was safe and effective.

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We do have 1-year results which are encouraging for low levels of myopia. We are continuing the study to find out what the long-term results are. I think this is a terribly important activity for the National Eye Institute to be involved in. I think we do have a responsibility to the American public to determine whether this procedure is of benefit.

Senator PROXMIRE. Thank you, Dr. Kupfer.

Mr. Chairman, I have some questions for Dr. Alexander I can ask at any time at your convenience.

GLAUCOMA

Senator WEICKER. Why don't we finish with Dr. Kupfer, and then I will allow you to ask your questions of Dr. Alexander.

Your recently completed report on glaucoma indicates that most people with this disease are adequately identified and treated and blindness is prevented. How many people lose their vision each year due to lack of early recognition?

Dr. KUPFER. We would estimate that probably about 5,000 individuals lose sight each year despite surgical and medical treatment of glaucoma. This takes into account the fact that there are somewhere between 1 and 2 million people under treatment, so that this represents a very small percentage who actually lose vision. These are people who are identified as being treated.

I would say that the vast majority of patients who do lose vision are those who are receiving treatment—who are under the care of an ophthalmologist, and we do not understand why in these cases, even though their pressures are brought into normal range, they continue to lose visual function. I think this is a very important question that we are trying to address.

Senator WEICKER. The report outlines for us what work must be done, and indicates that NEI would need an additional $6.5 million a year over the next 5 years to reach its goals. How much are you presently requesting for fiscal year 1986 for glaucoma research?

Dr. KUPFER. In fiscal 1986, we are asking approximately $13 million to support the Glaucoma Program.

Senator WEICKER. You touched upon the matter of cataracts. Where are we on this vis-a-vis the traditional surgery and new laser techniques?

CATARACT

Dr. KUPFER. Cataract surgery is probably one of the most successful of all medical operations. Approximately 700,000 cataract extractions are performed per year in the United States. The indications for cataract surgery are changing in the sense that cataract surgery is being done on the average in younger people with a better level of visual acuity than, let's say, was the case 20 years ago because the expectations of our elderly population are much greater; they want to continue to be able to drive their automobile, to read, to carry on work and, therefore, their visual requirements are much greater.

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The improvements in cataract surgery have continued through the last two decades with the development of better surgical techniques, use of the operating microscope, and most recently, with the use of the intraocular lens. All of these have significantly improved the quality of vision that follows the removal of the cataract. But this improvement has carried with it a markedly increased price tag because many of these technologic improvements have been very expensive.

The National Eye Institute's major thrust in the cataract research area is to try to slow the development of cataracts because not only are significant sums of money being spent on the treatment and rehabilitation of people with cataracts, but with the aging of the population, we are seeing a rapid increase in the number of cataract operations. Our goal is to find a way to slow the development of cataracts so people will be able to live their normal lifespans without needing cataract surgery. We calculated if we can delay the onset of cataracts by 10 years, we will be able to reduce by almost 50 percent the number of patients eventually needing cataract surgery. This is our major research thrust in this field.

Senator WEICKER. I have further questions for response, as do other Senators, for the record. I have no further questions at this time.

I thank you very much for your testimony.

What I would like to do vis-a-vis the schedule of witnesses is call Dr. Alexander in order that Senator Proxmire might ask questions of him. Immediately after Dr. Alexander, it will be my intention, Dr. Wyngaarden, to take up the Office of the Director, some questions at that time vis-a-vis the matter of the competing grants.

TEENAGE PREGNANCY PREVENTION

Senator PROXMIRE. Dr. Alexander, in your prepared statement you focus a substantial amount of your testimony on the subject of unwanted pregnancies and point out that one-half of all pregnancies in this country are either not wanted at all or not wanted when they occur. That is a tragic statistic, but even more tragic is a finding in a study released by the Guttmacher Institute, which promotes family planning, that 60 out of every 1,000 teenage women in America, or 6 percent, have had at least one abortion by the time they reach the age of 18. Furthermore, this is twice the rate in Sweden and France and nine times the rate in The Netherlands.

Finally, the United States was the only nation of the six studied in which abortion rates have been steadily rising for the past several years. I can't believe those other countries are producing superior contraceptives or have a lower rate of premarital sex. What are we doing wrong?

Dr. ALEXANDER. Senator Proxmire, the conclusion reached by the Guttmacher Institute report was basically that our levels of teenage sexual activity are comparable to those in these other countries. What is different is our pregnancy rate and that is primarily related to the nonuse of contraceptives by our teenage population. The conclusions in that report were that availability of contraceptives to our teenage population is significantly restricted compared to that in other countries, and

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that increased ease of access and availability to contraception would not increase the rate of sexual activity among teenagers, but would substantially diminish the rate of teenage pregnancy, possibly to a level quite comparable to those in other countries.

Senator PROXMIRE. The figures are so startling. Teenage abortions are performed in this country at nine times the rate in The Netherlands.

Dr. ALEXANDER. That is correct.

Senator PROXMIRE. Do you feel the availability of contraceptives might reduce unwanted pregnancies by something like that degree.

Dr. ALEXANDER. Possibly not to the degree in The Netherlands. There are other factors involved as well. But the primary conclusion of the Guttmacher report, and this is substantiated by other studies as well, is that increased access and ease of access to contraceptives, and increased availability of sex education to the teenage population would not increase sexual activity among teenagers, but would reduce our problem of teenage pregnancies.

Senator PROXMIRE. You say that conclusion is substantiated and you have received the report. What are you doing with the report, if anything?

Dr. ALEXANDER. We have within our staff developed a special initiative in contraceptive development. This includes both research to improve our existing array of contraceptives including some that are particularly useful for teenagers, as well as some additional behavior research studies on reasons for use, nonuse or incorrect use of contraceptives.

There is a separate component in the behavioral sciences area in this initiative. That is where we think we need to put a lot of effort.

Senator PROXMIRE. The problem is a matter of education.

Dr. ALEXANDER. It is in part education; it is in part access and availability.

INTERRACIAL FRIENDLINESS STUDY

Senator PROXMIRE. At a time when we are being told there is not enough support for vital research into such diseases as cancer and multiple sclerosis, I think we have a special obligation to see that NIH's funds are being well spent. So I would like to direct your attention to some specific studies funded by the Institute because, frankly, I don't understand generally how the work being done can be considered biomedical research and, more specifically, how it can contribute to the health of the American people.

For example, you awarded $432,000 plus indirect costs to Notre Dame for a 2-year study entitled, "Determination of Students' Interracial Friendliness." Apparently the purpose of the research was "to identify characteristics of students and of their school environments that affect friendliness between black and white students in designated classrooms."

Friendship choice was to be determined by having students circle words like "best friend," "friend," "know," "don't know," and so on. Teachers provided information on the classroom atmosphere.

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How does this research fit into the mandate of your institute, and how will the results be used?

Dr. ALEXANDER. Senator, I am glad to have a chance to address that question. I think it is important to understand the context of that grant in relation to our other research and the mission of the Institute. Remember, the Institute is not just child health, but human development as well. And our mandate given to us by both the executive branch and the Congress includes behavior studies in normal human development.

The social and affective development of children is a major component of the behavior sciences research supported by this Institute. In that context, it is hard to imagine a more relevant contemporary issue than the factors that enhance or impede the development of interracial friendliness among children in a public elementary school. If there is a place to put our focus on improving interracial friendliness, that is probably it. This study looked at elementary grades to examine different racial mixes in the classroom, ranging from nearly all black to nearly all white and all gradations in between—different school environments, different classroom types, different teacher types—and it measured friendship choices among children at the beginning of the year and at several points during the year.

What they are trying to do is correlate improved interracial friendship among the children with the racial mix in the classroom, the classroom type, the teacher type, the kind of environment these children are in. We hope to learn how these characteristics are related to factors that either impede or promote interracial friendship.

Senator PROXMIRE. I understand that. I think the project has a great deal of obvious merit, but what are you going to do with the results? Are you really going to use them? Do you think this is information that could be used to improve the relationships between the races? If it could, it would be a marvelous achievement. But I don't understand quite how you are going to use the study results effectively.

Dr. ALEXANDER. We would hope, sir, that it would be useful for school districts as they try to determine the type of racial mix in classrooms that would enhance learning as well as interracial friendliness, the kind of classroom situation that is appropriate to enhance this objective, and it would be useful in the educational system to achieve these objectives.

Senator PROXMIRE. Are your coordinating your activities with the Department of Education to assure that the results are used?

Dr. ALEXANDER. This study is just beginning, and we certainly plan to make that information available widely.

STUDY OF THE HIGH SCHOOL CLASS OF 1972

Senator PROXMIRE. Another project that will cost $952,000, plus indirect costs, over 5 years is called analysis of family event histories of the high school class of 1972. The project will investigate how an individual's living arrangements and family structure interact with his or her income and time resources. What relevance does this work have to your mission, and how will the results be used?

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Dr. ALEXANDER. This one does relate very directly to the Department of Education and utilizes a study it started back in 1972 through the National Center for Education Statistics. This is an example of how we can save money by piggybacking onto a survey already under way and ask some questions of specific relevance to us, taking advantage of, in this case, a $15 million data set that has been collected over the years.

The original intent of this survey was to look at how high school graduates turn their educational achievements from various curricula into jobs and earnings, and to study this over a long period of time. It is a sample of about 22,000 students nationwide.

We are adding to this survey, which will be done next year, questions relating to family status and household formation and breakup. What we hope to be able to do is relate the valuable education information and background information already obtained in this sample to issues of household formation, age of childbearing, economic factors interacting with childbearing, divorce, and child custody and support questions.

Senator PROXMIRE. Why is this important? It relates to more than population change.

Dr. ALEXANDER. The Institute is making a special effort to study family and household structure and the way they influence child development because of what the demographic statistics are telling us. There is no question that the family has a profound impact on the development of the child.

Since 1970, one-half of all new households that have been formed have been nontraditional households. That is, they are not two-parent households. Our statistics indicate that for a child born in 1980, by age 18, 70 percent of white children and 94 percent of black children will have spent at least part of their childhood in a single-parent family. This will amount to an average of one-third of their childhood years for white children and 60 percent of their childhood years for black children. That is a major change in our child-rearing patterns in this country, and it could have significant implications for child development.

Therefore, we think it is important for us to study this topic, and this is one part of a package of studies relating to family and household structure and change and their impact on child development.

Senator PROXMIRE. Dr. Alexander, I appreciate this information. You have given us a very good explanation of the project. I would appreciate it if you could provide for the record any further information you have on how you are going to follow up on this research, how it is going to be used, because the research could produce valuable information if it is put to use.

There are two other grants I want to ask you about for the record. One is a study of the formation process of Haitian ethnic organizations, and the other is entitled "Illegal Mexican Migrants and Mexican American Earnings." The latter project seems to be more related to the problem of immigration than health, but I am sure it has a health component. Again, in both those cases I wish you would provide for us your understanding of how the research is going to be used because, as I say, this is useful information only if we follow up on it very vigorously.

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Dr. ALEXANDER. I will be glad to provide that for the record, sir.
[The information follows:]

FORMATION PROCESS OF HAITIAN ETHNIC ORGANIZATIONS

The National Institute of Child Health and Human Development has a mandate from both the Congress and the executive branch to conduct and support research on the behavioral and sociological aspects of population growth. There are three components of population change: births, deaths, and migration. Legal immigration currently accounts for one-third of the population growth in the United States, and illegal immigration is at least equal to that and is probably increasing. Thus, for the Institute to study population and ignore immigration would mean leaving out a major component of the topic. There is much to learn from studies of migration. Studying migration in relation to cancer has shed light on environmental and genetic factors in several cancers. The same is true for heart disease, especially in relation to dietary effects as migrants adapt.

In population research, we are interested in migration for several reasons. First, we are interested in its initial contribution to population growth, and its secondary effect on population growth as immigrants have children. In addition to this growth, we are interested in the process called adaptation—that is, whether and how quickly immigrants abandon the reproductive patterns of their mother country and take on those of their new country, and the implications of this adaptation for growth and modification of the population. We are also interested in the effects on the health care system of the demands placed on it by immigrants who tend to have more illnesses and less financial resources. Haitian immigrants are of special interest in this regard due to their higher incidence of AIDS. We are also interested in the relation of the economic well-being of the immigrant family to child development. This particular study focuses on the role of ethnic organizations in facilitating or impeding that adaptation process. Analysis of the process by which immigrants adapt to the United States will provide lessons regarding ways to speed or facilitate that process and avoid undue reliance on nonethnic organizations.

ILLEGAL MEXICAN MIGRANTS AND MEXICAN AMERICAN EARNINGS

Illegal immigration is probably the major component of population change in certain areas of the United States. Illegal immigration from Mexico accounts for about 60 percent of the total amount of illegal immigration and, therefore, is a subject of much interest. This project will attempt to estimate the size of the illegal population of Mexican aliens in 1980 by using census data from the periods 1970–80. This is a very cost-effective approach because it will obtain the most information out of existing data and avoid the expensive task of gathering new data.

Illegal immigration has many effects on the health and well-being of the resident population. Some effects are directly visible, such as the overloading of emergency medical services in communities containing concentrations of Mexican Americans. Illegal immigration also has many indirect effects. The most important of these indirect effects is on employment and earnings of resident minority groups. Employment gives access to income and benefits such as medical insurance and these, in turn, determine the conditions which either promote or detract from the health and well-being of these communities, including effects on child health and development. This project will address the question of whether the existence of significant numbers of illegal Mexican migrants deprives legal resident Mexicans and other minority group members of the economic means to a healthy and prosperous life.

REVIEW OF COMPTROLLER GENERAL'S OPINION

Senator WEICKER. Thank you very much, Dr. Alexander.

Dr. Wyngaarden, if I could proceed with questions so far as you are concerned and then we will get back on track. I have two sets of questions that fall outside the normal scope of the hearing. Please have anybody come up with you.

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First, have you had an opportunity or has counsel had an opportunity to review the GAO letter, or is it still in the process of review and could you bring us up to date?

Dr. WYNGAARDEN. Yes; I read the Comptroller General's opinions, and we distributed it throughout the Institute. In addition, the HHS General Counsel is reviewing the opinion as noted in the Comptroller General's letter. Neither the Department nor OMB has had the opportunity to comment formally or reply to the opinion.

My understanding is that the administration does plan to respond formally to that opinion. I can still assure you that we do not plan to make any multiyear awards until this issue is resolved.

Senator WEICKER. Just as soon as you have something on that, if you would be back in touch. I would like to go a little further, though, if I might. It is my understanding that the OMB directive has already caused some major problems with investigators relative to ongoing research projects. Some of these projects that have been supported for 10 to 15 years costs anywhere between $500,000 and $1 million are being stopped because of the forced reduction in grant numbers and in some cases highly trained technicians are being lost due to loss of salaries. My questions are as follows: First of all, is my statement accurate?

Dr. WYNGAARDEN. I have heard such comments. I don't think we have any formal or accurate assessment of the impact, but I have heard those same comments, yes.

Senator WEICKER. What will happen to a longstanding productive research project if it loses funding due to the OMB directive?

Dr. WYNGAARDEN. This fiscal year started with one set of funding assumptions which changed after about one-third of the grant processing had actually taken place. We made awards from the first council round based on one assumption; then the revision of the 1985 budget was proposed and we must hold back substantially on the numbers of awards made in the second two council rounds. The result is that we will fund to much lower priority scores in those rounds.

This does mean that some of the informal advice given to grantees that they were likely to be funded was changed. We had to say with the change in funding policy they may not be funded. There are investigators who, unfortunately, were led to think that their project would be funded and that may now be different. There were in that category, of course, both competing renewals and first-time applicants. So some of these individuals who have been funded for 10 years may fall just beyond that cutoff under the revised budget, whereas it would have been included under the former set of assumptions.

To that extent, your statement is correct that there would be a group of investigators whose grants are now at risk of being terminated, unless we can find some way of extending them administratively for the short term.

Senator WEICKER. When you start funding at the 6,500 level, what kind of administrative pressure will you be under? I am not talking about the administration. I am talking about, in other words, your staff.

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Dr. WYNGAARDEN. It depends on when this issue is resolved. I believe I mentioned that Secretary Heckler has assured the Congress that we would not under any situation make any multiyear awards at least until June 1. I was asked in the House whether we could delay until September 1. I said, yes, we could. But that would put us under a great deal of pressure to make the remaining awards in 1 month's period of time. But we could do it.

Senator WEICKER. In other words, assuming for a minute that my assumption of the 6,500, I am not saying you are agreeing. I am saying that is my assumption in the course of this question, would you have to pay overtime to your staff in order to award the grants before the end of the year?

Dr. WYNGAARDEN. May I ask Dr. Raub to comment on that?

Dr. RAUB. It is possible we would, Senator, but that should not be a first order problem, that under either of the scenarios you just discussed, we should be able to ensure that the awards are made and that they are made under the standards of administrative quality that we always strive for.

Senator WEICKER. It seems to me you could very well end up with the OMB directive costing instead of saving, especially if you get into the administrative stance I alluded to.

Dr. WYNGAARDEN. If it is not resolved until September 1, then the month of September we will be very busy under any situation, regardless of which directives we receive.

Senator WEICKER. My suggestion is that I get back to really the thrust of my first question, the uncertainty that this is causing in the scientific community. I think that is probably the worst aspect.

Dr. WYNGAARDEN. Yes; it is.

Senator WEICKER. It would seem to me this is a matter which should be resolved fairly soon. I think it would be a bad mistake scientifically to allow this to get caught in the tug of war that will be going on for the next several months between the Congress and the executive branch over the overall budget.

Dr. WYNGAARDEN. There is no question the uncertainty has created a great deal of mental anguish in the scientific community. I agree with you the sooner it can be resolved the better. I think that is a more important issue than the mechanics of dealing with the problem at the NIH level.

Senator WEICKER. Why don't we try to target—if indeed no resolution or no position has been taken by the administration, relative to the GAO letter, by the end of the Easter recess, it would be my recommendaton that we all meet shortly thereafter in an attempt to see whether this aspect can be resolved.

Dr. WYNGAARDEN. I will be happy to convey that information to the Department.

Senator WEICKER. I have another function aside from being the chairman of the appropriations Subcommittee on Labor, HHS, and that is being chairman of the Senate Small Business Committee. I have got a

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question or two here that I am going to ask in the hopes of performing a useful function in getting at least these two agencies together as really the law requires. As you know, Public Law 97-219 requires 11 Federal agencies to set aside a percentage of their research and development budgets for small innovative firms. NIH is the second largest participant in this program, which the Small Business Administration oversees. Since implementation, since 1982, it is my understanding SBA officials have written on a number of occasions expressing concerns the way NIH has implemented the law. SBA has noted solicitations are written vaguely, requests unsolicited proposals, evaluation process is exceeding the 6-month limitation. Are you aware of SBA's concerns?

Dr. WYNGAARDEN. Yes; I am, and the SBIR Program for the NIH is administered from Dr. Raub's office, and he is thoroughly familiar with all of these issues.

Dr. RAUB. Certainly I say we have responded on many occasions in detail and continue to work with the Small Business Administration in attempting to reconcile the objectives of the law with the mission and the underlying statutes of the NIH.

Dr. WYNGAARDEN. I can comment on one point——

Senator WEICKER [interposing]. Let me say this, regardless of all the detailed questions the staff has given me here, I have tracked this thing for the last several months in a general way. I have got to say to you that I hear that really people in NIH sort of feel this is below the standard that they like to feel is appropriate in the matter of awards; people at SBA feel they have been given the runaround.

Look, I want to make it work, and it clearly has got some difficulties. I would hope, as I have already expressed my opinion of you, Dr. Wyngaarden, which is nothing but the highest. I also expressed my opinion of respect for Jim Sanders who is doing an outstanding job over at the Small Business Administration. I think it is more really a matter of attitude in both the agencies. I am not talking about you or Jim Sanders. And I would hope that we could—you and the Director and myself—could sit down and chat generally about this matter. I don't think we are gong to get anywhere by belaboring any individual or any institute. But surely a few things are falling between the cracks here, and it is not working the way the law intends.

Dr. WYNGAARDEN. We want to make it work also. In our opinion, it is working. Our initial contact with the small business community disclosed a certain unfamiliarity with the mission of the NIH and also with the differences between the grant mechanism, which we primarily employ, and that of contracts. Many came expecting to be informed as to exactly what product we were after and our style is quite different from that, as you know. We are primarily dependent upon the ideas generated by the scientific community. We presented this as an opportunity for them to tell us what they would like to do that would be useful to them and fall within our mission. I think we have made a lot of progress with that. There is no question that the priority scores of some of the projects we have supported are lower than the average at the NIH,

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but I would hasten to add there is nothing unusual about that for a new program.

If we look at new institutes that were created, this is commonly the case until the scientific momentum in that area catches up with that of the NIH in general, and I have no question this will happen in the small business community as well. But we are not discouraged at all.

Senator WEICKER. All right. I want to make it work. I think we are all on the same line of thought and I will discuss it with you further.

Dr. WYNGAARDEN. I will be happy to do that.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. The questions that I referred to earlier will be sent to you for your response and inserted in the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Question: Your recently completed report on glaucoma indicates that most people with this disease are adequately identified and treated, and that blindness is prevented.

The report outlines for us what work must be done and indicates that the NEI would need an additional $6.5 million a year over the next five years to reach its goal. How much are you presently requesting for FY 1986?

Answer: The FY 1986 request for glaucoma research is $13,191,000.

Question: Are you going to request additional funding in FY 1986?

Answer: No, we will not request additional funding.

Question: Is there a pool of talented researchers available to take advantage of the extra funding?

Answer: There are a number of glaucoma researchers working in areas related to the initiatives described in the report. These investigators could easily expand their efforts to address the specific goals that the report identifies. In addition, we believe that other scientists whose work is not primarily in glaucoma research but in related areas, would be interested in redirecting their efforts toward the goals specified in the report. Some of these goals, particularly the clinical trials and epidemiologic studies, would require extensive planning before they could be implemented.

1985 BUDGET

Question: I note, Dr. Kupfer, you are not losing any centers this year. But, you are losing 91 research project grants. What areas of research will be affected by this cut?

Answer: It is not possible to identify specific projects that would be affected by this cut. The reductions will probably cut across all of the programs in the Institute.

Question: What has the effect been on the community of scientists that depend upon your Institute for support for their research?

Answer: The loss of 91 competing research grants has caused a great deal of concern in the vision research community. Because the NEI uses the research project grant mechanism (R01) as essentially its only mechanism of grant support, any reduction in the number of awards of this type has a disproportionate impact on the vision research community. Other support mechanisms such as large research centers are not available to the vision research community.

PREVENTION-RELATED ACTIVITIES

Question: In response to my priorities' question during last year's hearings, you responded that the rapid application of what is

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learned in the lab to try to affect either prevention or treatment of disease is your highest priority.

What are your efforts in the area of prevention?

Answer: Here are some of the major prevention-related activities of the NEI:

o Research aimed at the prevention of proliferative diabetic retinopathy. One of the leading causes of blindness in the United States today is the diabetes-associated retinal disease called diabetic retinopathy. This disease poses the greatest risk to sight when it enters the so-called proliferative phase, in which new blood vessels begin to grow on the retina. The NEI is supporting a major clinical trial, the Early Treatment Diabetic Retinopathy Study (ETDRS), to determine whether laser treatment in the pre-proliferative or early proliferative phases of diabetic retinopathy can slow or halt the progression of the disease and yield even better visual results than laser therapy used later in the course of the disease. The ETDRS completed enrollment of patients in March 1985. Also, the NEI is cooperating with the pharmaceutical firm Pfizer, Inc. in another nationwide clinical study called the Sorbinil Retinopathy Trial. This study will determine whether sorbinil, a new medication that is in a class of drugs called aldose reductase inhibitors, can slow or block the development of diabetes-related eye and nerve changes in diabetics who do not yet have these problems. Patients being enrolled for the study are insulin-dependent diabetics who are at high risk of developing diabetic retinopathy and neuropathy (nerve disease). If sorbinil proves effective, this may mean that the onset of diabetic complications can be prevented by means that are independent of the control of blood sugar.

o Research to prevent aging-related cataract. Last year in the United States, more than 700,000 cataract operations were performed, and the number is increasing annually. At present, surgery is the only treatment proven effective for cataract, and there is no known means of preventing the disorder or slowing its progression. NEI is supporting a wide range of studies related to cataract prevention. These include epidemiological studies aimed at determining what risk factors might predispose a person to developing cataract. Also included are laboratory studies aimed at understanding, and finding means to counteract, the changes that occur in the lens with advancing age and prolonged exposure to light or other environmental influences.

o Research to prevent hereditary and developmental degenerations of the retina. Each year, many people--most of them children and young adults--suffer serious visual loss from hereditary retinal degenerations. The most common of these are the retinitis pigmentosas, a family of diseases that cause inexorable visual loss ending in blindness. The NEI is supporting clinical and laboratory research to uncover the biochemical mechanisms responsible for the retinitis pigmentosas in humans and similar diseases occurring in animals, in the hope of obtaining information that will permit the development of specific treatments. Also, NEI scientists are studying the molecular biology of another hereditary retinal degeneration whose biochemical basis is much better known.

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This disease--gyrate atrophy--is associated with a deficiency of a particular enzyme called ornithine aminotransferase (OAT). The aminotransferase investigators are now on the verge of cloning the gene that codes for OAT. These advances may eventually lead to the development of a gene therapy for gyrate atrophy.

o Research to prevent retrolental fibroplasia and other proliferative retinopathies. Improved survival of very small premature infants has resulted in a resurgence of retrolental fibroplasia (RLF), a potentially blinding eye disease that is associated with increased environmental oxygen levels (as in incubators) and increased susceptibility to oxygen within the blood vessels of the eye. NEI-supported studies are aimed at better understanding the role of oxygen in RLF and finding means of altering blood-vessel susceptibility to oxygen.

o Research to prevent ocular inflammations. NEI-supported investigators are probing into the underlying mechanisms of uveitis (inflammation of the inner eye) and inflammatory diseases of the cornea to discover the immune mechanisms that are involved in these sight-threatening conditions and, wherever possible, to learn how to short-circuit the inflammatory process. The aim is to uncover information that will allow the prevention of recurrences and perhaps even initial episodes of these disorders. NEI studies in ocular immunology have already shown that the drug cyclosporine is a promising agent for controlling autoimmune uveitis and preventing its recurrence.

o Research for the prevention of macular diseases and their consequences. Age-related macular disease is the leading cause of new cases of blindness in people age 65 and over. A few years ago, a nationwide clinical trial supported by the NEI showed that appropriately timed laser treatment can reduce the risk of severe visual loss by 90 percent in people with the neovascular form of age-related macular degeneration. Research continues in an effort to learn how to prevent this and other forms of macular degeneration. Much of this research consists of basic studies on the effects of aging, light, and oxidation on the metabolism and control new vessel growth.

o Research to prevent recurrent corneal infections from herpes simplex virus. Recurrent corneal infection from herpes simplex virus is a serious and highly prevalent cause of visual impairment and disability in the United States. NEI-sponsored research on herpes emphasizes the characteristics of the virus and host cell that determine when or whether an infection will recur. Studies are now underway in animals and patients to test the efficacy of new antiviral compounds in preventing recurrence of ocular herpes infection. Alternative methods of administering antiviral compounds are also being investigated.

o Identification of risk factors for the development of glaucoma. An estimated 2 million Americans have glaucoma. The NEI is conducting clinical and laboratory studies to define genetic, racial, and environmental risk factors for the development of damage to the optic nerve in glaucoma and to determine the reasons for the varying susceptibilities of individual eyes to optic nerve damage.

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o Development of new drugs and treatments for the prevention of visual loss from glaucoma. The NEI is supporting research to better understand the regulation of fluid inflow and outflow in the front part of the eye, the control of intraocular pressure, the alteration of these processes in glaucoma, and the effects of a variety of drugs on fluid dynamics within the eye. Also, the NEI has initiated a nationwide clinical study, the Glaucoma Laser Trial, to determine how laser treatment compares with conventional therapy in the care of patients with newly diagnosed glaucoma.

o Research related to the prevention of amblyopia and strabismus. More than 4 percent of the U.S. population has visual impairment due to disorders of the central visual pathways. The NEI is supporting research on normal and abnormal visual development. NEI-supported investigators are attempting to learn how abnormal visual input during early life brings about inadequate development of the visual pathways and the brain's visual centers. The investigators are also trying to determine if such abnormalities are reversible with treatment.

o Prevention of blindness from branch vein occlusion. Occlusion of a branch of a retinal vessel is a potentially blinding condition that can occur as a complication of hypertension, atherosclerosis, and other diseases that interfere with the health of blood vessels. The NEI is funding basic research on the effects of cholesterol levels on the retinal blood vessels. Also, a multicenter clinical trial supported by the NEI is studying the natural history of branch vein occlusion and evaluating the effectiveness of laser treatment in this disorder. The study has already shown that laser treatment can help to reduce the macular swelling that occurs in many people with branch vein occlusion.

o Research to prevent visual loss and discomfort from ocular chlamydial infections. Trachoma, a disease caused by chlamydial infection, is the world's leading cause of blindness. In the United States, chlamydial infection is generally considered to be a venereal rather than an ocular disease. However, chlamydial conjunctivitis (infection of the membranes at the front of the eye) is a significant cause of discomfort, temporary visual disability, and medical expense. NEI-sponsored studies related to the prevention of trachoma and chlamydial conjunctivitis include studies of the ocular immunology of chlamydial infection and research to overcome the problems involved in vaccine development.

o Research for the prevention of visual impairment from corneal burns and ulcers. Corneal burns and other ocular surface abnormalities often lead to chronic pain, severe visual disability, and frequently, total blindness. The NEI is currently supporting a clinical trial to evaluate the usefulness of ascorbic and citric acid therapy in alkali burns of the eye. Also, studies of epithelial wound healing and factors that may facilitate it are now underway with NEI support.

o Research to prevent nearsightedness and other refractive errors. The NEI is supporting experimental studies of normal and abnormal growth of the optical components of the eye to obtain information that will be of value in understanding the development of refractive errors, and ultimately in discovering ways to prevent them.

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PREVENTION SUCCESSES

Question: Can you describe some of the successes in this area?

Answer: Federally supported research on blinding diseases has yielded a number of sight-saving discoveries. Some research accomplishments of major medical significance are as follows:

a) The NEI-supported Diabetic Retinopathy Study showed that laser treatment can lower the risk of blindness by 60 percent in people with moderately advanced or advanced diabetic retinopathy.

b) The Senile Macular Degeneration Study, another nationwide clinical trial supported by the NEI, showed that laser treatment delays the onset of bilateral blindness in almost 90 percent of people who have neovascular senile macular degeneration in both eyes.

c) Laser iridotomy, an outpatient procedure developed through research, is being used increasingly in place of conventional surgery to relieve pain and prevent blindness from angle-closure glaucoma.

d) In 1952, an NIH-supported clinical trial showed that retrolental fibroplasia, a blinding disease that had become epidemic among premature infants, could be largely prevented by reducing the level of oxygen in incubators. At the time that the study findings were announced, there were 2,000 new cases of retrolental fibroplasia each year. Six years later, only 28 cases of this disease were reported.

e) Ocular histoplasmosis syndrome is a potentially blinding eye condition that can occur in people who have been exposed to the fungus histoplasma, which is very common in the midwestern and southern United States. Last year, the NEI-supported Ocular Histoplasmosis Study showed that appropriately timed laser treatment dramatically reduces the risk of severe visual loss from this disease. It is estimated that laser treatment combined with follow-up care may each year prevent as many as 2,000 cases of serious visual loss caused by this disease.

There is good reason to believe that vision research will continue to be as productive and cost-effective in the future as it has been in the past. This expectation is based on advances such as these:

a) NEI scientists have found that cyclosporine, a new immunosuppressant drug, holds great promise as a treatment for uveitis, an inflammatory disease that is a leading cause of visual impairment in this country.

b) Recent laboratory research suggests that in the future it may be possible to slow cataract formation in humans, and thus reduce the number of cataract operations needed each year.

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c) Recent research suggests that aldose reductase inhibitors, a class of drugs developed and intensively studied at the NEI, have the potential of preventing several of the most devastating complications of diabetes. The NEI is now collaborating in a clinical trial to determine whether [illegible]dose reductase inhibitor called sorbinil can prevent or de[illegible] the development of diabetic retinopathy in insulin-dependent [illegible]abetics.

COST SAVINGS DU[illegible] TO PREVENTION

Question: Can you estimate how much money is saved annually by the appropriate application of prevention research?

Answer: It is probable that the annual savings to be realized from the application of research discoveries already proven to have sight-saving value is approximately $800 million, and that this total may be greatly increased by future application of promising results just now emerging from laboratory and clinical research. Some of the savings already made possible by research directed at prevention of visual impairment are discussed below:

a) It has been estimated that full application of the findings from the Diabetic Retinopathy Study would yield net annual savings of $454 million. Also, it has been calculated that, if all those with the high-risk form of diabetic retinopathy had received laser treatment in the years since 1976, about 18,000 people would have been spared blindness.

b) The net annual savings that could be realized through laser treatment of people who have the most sight-threatening form of age-related macular degeneration is $57 million.

c) The net savings that could be realized through laser iridotomy treatment of the approximately 30,000 patients who undergo treatment for angle-closure glaucoma each year is $66 million.

d) The savings accrued over a ten-year period as a result of the study that proved the role of oxygen in blindness among premature infants have been estimated at $2 billion.

Here are some examples of research activities that are expected to yield significant and widespread clinical benefits in years to come:

a) If cyclosporine lives up to its expectations and proves effective in preventing 90 percent of the cases of blindness from uveitis, the net savings in the first year will be $28.9 million.

b) If the need for cataract surgery can be delayed by 10 years per patient, the number of cataract operations performed each year would be reduced by 45 percent. This would mean that 300,000 fewer cataract operations would be performed each year, for an annual savings of $465 million.

c) If the progression of diabetic retinopathy can be blocked or slowed by treatment with aldose reductase inhibitors or earlier

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laser treatment (another therapeutic option being evaluated in an NEI-supported clinical trial), the economic benefits would be signficant. Each year, an estimated 4700 diabetics go blind in spite of current treatment. It has been estimated that if the onset of blindness could be delayed for one year in 90 percent of these people, the savings for that year would be $100 million.

FUNDING FOR PREVENTION

Question: What percentage of your research dollars are directed toward prevention?

Answer: The NEI devotes 27 percent of its research budget to projects specifically aimed at prevention of eye disease or visual disability. However, many basic research projects which are not counted in this total undoubtedly will eventually yield findings of great relevance to prevention.

CATARACT SURGERY

Question: It is estimated that the cost of cataract surgery in the United States exceeds one billion dollars per year. Has your Institute conducted or supported any research which would reduce this cost? If so, could you briefly explain the nature of the research?

Answer: Yes, the NEI has supported some very important research that may eventually help to reduce the health care costs associated with cataract surgery. This research is directed at discovering the underlying mechanisms of cataract and developing methods of counteracting them, so that methods may be devised for slowing or halting the progression of cataract, or preventing it altogether. A major breakthrough occurred a few years ago, when NEI scientists showed that the diabetes-associated cataracts which develop in animals could be prevented with drugs known as aldose reductase inhibitors. Now NEI-supported scientists have obtained evidence suggesting that a chemical process called oxidation is one of the major culprits in the clouding of the lens that occurs in aging-associated cataract. The recent findings suggest that it may be possible to develop anti-oxidant drugs that will help to protect the lens from changes caused by oxidation.

Question: How much more would this cost be if recent advances in cataract surgery such as the use of the laser were not developed?

Answer: It is true that over the past two decades, advances in cataract surgery have steadily reduced the amount of time the average patient spends in the hospital or confined to bed after surgery. We cannot estimate the net savings involved, but we can guess that they must be substantial, in view of the fact that each year more than 700,000 patients undergo cataract surgery.

However, the technological advances that have commanded the greatest attention in this area of surgery over the past few years have not, in general, brought about a reduction in surgical costs. These innovations, which include increasing reliance on the intraocular lens as a means of substituting for the natural lens

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removed during surgery and widespread use of the YAG laser to treat "post-cataract" problems in people who have undergone cataract surgery, were not adopted to make cataract surgery more economical. Rather, their main impact has been to improve the quality of the outcome for many of the people who undergo the operation.

Nonetheless, there is a great deal that research can contribute to reduce the costs that cataract imposes on our Nation. The biggest cost savings will occur if scientists can find a means of slowing or halting the progression of cataract. The economic impact of such a discovery would be enormous. It has been estimated that if the need for cataract surgery could be delayed for ten years in the average patient, the number of operations each year could be reduced by 45 percent, for an annual savings of $465 million. The NEI is now supporting research on the biochemistry and epidemiology of cataract, in the hope of obtaining the detailed information about causative factors that will be needed to make prevention a reality.

ACQUIRED IMMUNE DEFICIENCY SYNDROME

Question: It is well established that AIDS patients suffer from viral infections of the retina. Would you please describe for us the type of research your Institute funded on AIDS during the past year.

Answer: One of the most frequent of the opportunistic infections occurring in patients with AIDS is cytomegalovirus (CMV) infection. When the body's immune system is weakened by AIDS, the CMV virus may invade the retina of the eye, and often attacks vital organs as well. NEI-supported investigators have found that the AIDS patients with CMV retinal infection are the ones who are at greatest risk of dying within a few months, apparently because they are in a very severely immunosuppressed state.

NEI investigators at the NIH Clinical Center have been studying AIDS patients for characteristics that might indicate which of them are at greatest risk of developing CMV retinitis. They have found that those AIDS patients with a low count of certain types of white blood cells are the ones most likely to develop the retinal infection. In another study, they have obtained some evidence indicating that the CMV retinitis may develop in a sequence of stages which can be monitored.

NEI intramural scientists are cooperating with medical investigators from other NIH institutes in evaluating antiviral drug therapy for AIDS-associated CMV infection and are planning to cooperate in studies of other aggressive pharmacological therapies which might prolong, or even save, the lives of AIDS victims. In these studies, the extent of AIDS-related abnormalities detectable in the patients' eyes will be used as one indicator of the progression and severity of the overall disease. It is hoped that reversals of the ocular manifestations of the disease will provide an advance clue that therapy is working in some cases, and thus speed the pace of research in this area.

In addition to the NEI intramural scientists who are studying AIDS,

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several NEI extramural grantees conducting clinical research on ocular infections report that they are seeing AIDS patients and collaborating with AIDS researchers from other disciplines. Although no NEI funds are allocated specifically for these collaborative studies, they, too, are expected to yield significant information relevant to the prognosis and treatment of AIDS and its ocular complications.

Question: How many grants did you award last year for research in this area and how many will you award this year for research on AIDS?

Answer: In 1984 the NEI did not support any grants specifically for research on AIDS. The Institute will probably support one grant in this area in 1985. The primary focus of NEI-supported research on AIDS is in the intramural program, where NEI staff ophthalmologists collaborate with other physicians at the NIH Clinical Center in assessing the status of AIDS patients and the effectiveness of any treatments being administered to them. Recently NEI intramural scientists have collaborated with NIAID investigators in evaluating the effectiveness of antiviral drug therapy on cytomegalovirus (CMV) retinitis, a viral infection of the retina that occurs in many AIDS patients. This pattern of cooperation is also reflected in the work of a few NEI grantees who are funded for research on diseases other than AIDS but who take advantage of opportunities to collaborate with other specialists at their institutions who are caring for AIDS patients and conducting research in this field.

Question: How many more should you be funding?

Answer: At present, many eye-related problems that accompany AIDS are being studied collaboratively in the broadly focussed grants supported by other Institutes that I referred to earlier. There are not yet many applications being submitted specifically for research on the ocular complications of AIDS. However, the NEI would fund high quality meritorious approved grant applications for AIDS research that are referred to it.

Question: During last year's hearings you talked about using the techniques of molecular biology to study certain eye diseases. Can you describe the progress you have made in this area?

Answer: Encouraging the application of molecular biological techniques to vision research is one of our highest priorities. The tools that modern molecular biology has placed in the hands of today's medical researcher provide, in many cases, the opportunity to understand the molecular basis of the disease process itself. There is a very real possibility that the actual genes responsible for a variety of hereditary eye diseases will be isolated and characterized. This would open the way for gene therapy--the actual replacement of the defective gene with a normal one--or improved treatment directed at the identified biochemical defect(s), and better methods of genetic screening and counseling of individuals at risk for these diseases.

NEI-supported grantees continue to make significant progress in the identification of the gene defect responsible for retinoblastoma, a sight- and potentially life-threatening cancer of

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the retina which develops in early childhood. Researchers have determined, using molecular biological techniques, that the gene defect responsible for retinoblastoma is located in a particular region known as the q14 band of chromosome 13. Additional research has provided evidence that retinoblastoma may result fro the development of homozygous or identical gene abnormalities in corresponding regions of this chromosome. The localization of this gene brings us a step closer to its identification and characterization which may allow us to prevent the disease process through gene therapy.

Investigations are still in progress to isolate a molecular probe or marker for human ornithine aminotransferase (OAT), the enzyme responsible for converting the amino acid ornithine into the amino acid arginine which is used in the synthesis of proteins. This probe would be used to study OAT gene defect(s) present in patients with gyrate atrophy, a hereditary disease in which blindness occurs as a result of progressive degeneration of the retina and the underlying vascular tissue, the choroid. NEI intramural scientists are also trying to identify a genetic marker for the location of the gene responsible for one form of retinitis pigmentosa, a disease characterized by the deterioration of the photoreceptors or light-sensitive cells of the retina.

Both intramural and extramural scientists supported by the NEI are using the techniques of molecular genetics to study various important proteins of the eye. One such group of proteins, the crystallins, contains the major protein components of the lens, which becomes opaque during the formation of a cataract. Crystallin genes from animal models have been isolated and have been used to produce in cell culture their own particular types of crystallins. Analyses of these crystallins have helped in the isolation of human crystallins and have allowed comparison of the crystallins of different species. Studies of the structure and function of the crystallin genes and their products should help us to understand better the mechanisms involved in the maintenance of normal lens transparency and the development of cataracts.

The application of recombinant DNA technology has allowed the cloning of the S-antigen which is believed to be responsible for autoimmune uveitis. This highly destructive inflammatory disease of the retina and choroid is characterized by the accumulation of inflammatory cells and fluid within the eye. The ability to produce large amounts of human S-antigen through this technology will allow scientists to study the structure and function of S-antigen and also the autoimmune mechanism of the disease process.

The field of molecular biology has also provided us with a variety of sensitive techniques which should help us learn a great deal about other molecular mechanisms involved in eye disease. We hope this new understanding will be quickly translated into an improvement in the quality of life for the many who suffer from these diseases.

Question: Will your FY 1986 funding level allow you to continue this research?

Answer: The FY 1986 funding level will allow the National

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Eye Institute to continue research in priority areas that involve using the techniques of molecular biology to study important ocular diseases.

FULL-TIME EQUIVALENTS

Question: Your budget request shows a reduction of 31 full-time equivalents (FTEs) since 1984. How many FTEs are necessary for high priority work, and what are their areas of opportunity?

Answer: The very highest priority work will be continued at the current staffing level. Some research programs that could be immediately launched by exploiting recent scientific breakthroughs but which maybe delayed somewhat at the the current level include:

(1) development of a gene therapy for uveitis, the inflammatory eye disease most likely to cause pernanent visual loss;

(2) development of a gene therapy for one form of retinal degeneration;

(3) development of a new drug to treat retinitis pigmentosa; and

(4) development of new methods of controlling aldose reductase, the enzyme involved in the formation of diabetic complications, with chemical inhibitors and with gene therapy.

GLAUCOMA SCREENING

Question: In your report on the Glaucoma Control Research Initiative you indicate that only 441 of the 166,454 people screened for glaucoma were found to have glaucoma. Is such a yield from screening cost effective?

Answer: We do not believe such a yield is cost effective.

Question: Could you summarize what your report suggests to address this problem?

Answer: Glaucoma screening programs are carried out sporadically and are viewed with very mixed enthusiasm because of the low yield that is generally achieved. Major limitations appear to rest in the currently used screening methods and in the perceived need to screen the population at large rather than concentrating on groups known to be at elevated risk. Our report recommends specific research that may help in evaluating the effectiveness of glaucoma screening in preventing visual loss. In addition, the report recommends a number of activities for the consideration of those groups and organizations in the private sector which currently carry out glaucoma screening programs. We plan to make this information known to such groups in the hope that these important issues can be addressed as glaucoma screening programs are continued or initiated.

SMALL GRANT PROGRAM

Question: Your FY 1986 budget includes $713,000 for small grants. You have indicated that this money would be used primarily to fund the research of young scientists who may have new ideas and

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approaches. Can you give us some indication of how successful this effort has been?

Answer: We are currently in the process of evaluating our Small Grants Program. The first awards were made only a few years ago and these grantees are now beginning to apply for full-sized research project grants. Our analysis will include an evaluation of the applications submitted, approved, disapproved, and funded for this group as well as those who were not previously funded under the Small Grants Program.

Question: How does one qualify for a small grant as compared to the larger grants?

Answer: Our program is designed to provide limited funding ($15,000 for direct costs) through a rapid review process (about three months) to those young investigators who feel the need to obtain pilot or feasibility data before competing for a research project grant. Any potential applicant who already has the necessary preliminary data is instead encouraged to apply for a larger grant, which usually is the individual research project grant (R01) or perhaps a new investigator research award (R23).

MULTIYEAR FUNDING

Question: Does the OMB-directed multi-year funding on research grants affect your ability to support good research?

Answer: It does only in the sense that a number of good grant proposals--91 in our case--will not be funded.

Question: But in the past you have favored a multi-year funding policy. What are the advantages and disadvantages of such a policy? How does it differ from the wizards at OMB?

Answer: During the mid 1970's the administration advanced a proposal in order to reduce future year budget requirements using current year funds. It was similar in concept to the multiyear funding proposal currently under discussion.

CLINICAL TRIALS

Question: Last year we provided your Institute with funding for 9 clinical trials. How many have been started?

Answer: To date we have started 7 new clinical trials this year. They are: Treatment of High-Risk Retinal Detachment; Cryotherapy for Severe Retrolental Fibroplasia; Eye Prophylaxis in the Newborn; 5-Fluorouracil and Glaucoma Filtering Surgery; Randomized Trial of Cyclosporine A in Corneal Transplantation; Randomized Study of Cyclosporine A in Uveitis; and Treatment of Retinitis in a Randomized Trial with DHPG (a guanine derivative) or Steroids.

Question: Do you expect all of them to begin this year?

Answer: Because of shifts in scientific opportunities and other changes that would be necessitated by the proposed multiyear

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funding plan, we do not expect that all of the 9 trials you refer to will begin this year. However, new scientific developments have allowed the addition of new trials to the original list; therefore, 12 new trials will be supported in 1985.

PROGRAM PLAN MID-COURSE REVIEW

Question: I understand that your vision research plan which was last revised in 1983 was due for a mid-course review. What is the status of that review?

Answer: The purpose of this evaluation is to update the Plan, recognizing the many new opportunities that now exist for research on blinding and disabling eye diseases as a result of the astounding progress that has been made in certain areas of biomedical science since the Plan was prepared. These areas include molecular biology, immunology, and neuroscience. The updated Plan will encourage current and future grantees to initiate high-priority scientific research in these and other important areas of vision research to solve the major problems of visual impairment, disability, and blindness that face our Nation today.

To accomplish the evaluation, the Council late last year charged five panels of scientific experts with the following tasks:

A. Review all the recommendations of the current Plan.

B. Review data that show in detail the actual NEI funding experience in FY 1982-1984.

C. Ask the following questions:

(1) Do the Plan's recommendations adequately address the full scope of current research in this field as well as those opportunities not yet exploited?

(2) Is there an appropriate balance of effort in the NEI's program in terms of the Institute's mission and the goals and objectives stated in the Plan?

(3) Are the Plan's original project recommendations for FY 1983 still appropriate for FY 1986-1987?

D. Update the Recommendations and resource needs projections, giving the rationale for any changes.

By this time, all of the Panels have met and carried out the above tasks. Rough first drafts of their reports have been prepared and reviewed and accepted by the National Advisory Eye Council. Panel members are now working on their final drafts which will be reviewed by the members of the Council's Program Planning Subcommittee and discussed at the full Council meeting at the end of May. Depending on the outcome of that review, Panel reports will either be accepted or revised. In any case, the final Midcourse Evaluation report is expected to be published this summer.

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Question: How does the tight budget situation impact on your plans?

Answer: It makes it all the more imperative to identify program priorities as well as those areas in which the level of funding is adequate and need not expand significantly over the next two years. Program priorities include those areas which must be protected in times of level or decreasing budgets as well as areas in which there is both great need and scientific opportunity for program development if additional funds become available. The Panels carrying out the Midcourse Evaluation have been told not to be overly concerned with possible budgetary restrictions, but to use their best professional judgment in identifying the most important research needs and opportunities. The latter task includes assessments of the adequacy of available manpower. That is, are there a sufficient number of investigators who could develop high quality grant applications in areas recommended for program development if funds were available for such research? Such considerations help assure that resource projections are kept within realistic and potentially achievable bounds.

Question: What does this review recommend for a budget in FY 1986?

Answer: The Council's budget recommendations will not be made until the final drafts of the Panel reports have been reviewed and approved.

PREVENTION

Question: In a speech before the American Pharmaceutical Association, Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: Here are some of the major prevention-related activities of the NEI:

- o Research aimed at the prevention of proliferative diabetic retinopathy.
- o Research to prevent aging-related cataract.
- o Research to prevent hereditary and developmental degenerations of the retina.
- o Research to prevent retrolental fibroplasia and other proliferative retinopathies.
- o Research to prevent ocular inflammations.
- o Research for the prevention of macular diseases and their consequences.
- o Research to prevent recurrent corneal infections from herpes simplex virus.
- o Identification of risk factors for the development of glaucoma.

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- Development of new drugs and treatments for the prevention of visual loss from glaucoma.
- Research related to the prevention of amblyopia and strabismus.
- Prevention of blindness from branch vein occlusion.
- Research to prevent visual loss and discomfort from ocular chlamydial infections.
- Research for the prevention of visual impairment from corneal burns and ulcers.
- Research to prevent nearsightedness and other refractive errors.

FUNDING FOR PREVENTION

Question: What percent of your budget is directed to preventive research?

Answer: The NEI devotes 27 percent of its research budget to projects specifically aimed at prevention of eye disease or visual disability. However, many basic research projects which are not counted in this total undoubtedly will eventually yield findings of great relevance to prevention.

INFORMING PUBLIC OF RESEARCH RESULTS

Question: How are the results of this research being translated into useful public information?

Answer: The NEI has made a major effort to inform the public and physicians about new clinical discoveries that can prevent visual loss. For example, the public information and education campaign for prevention of blindness from diabetic retinopathy--a project in which the NEI has engaged the cooperation of other government and numerous private organizations--is perhaps the most extensive campaign undertaken for any eye disease. It aims at educating diabetics and their families about the dangers that diabetes can pose to the eye and about the availability of a treatment that can save the vision of many people whose sight is threatened by complications of diabetes. Another goal of the campaign is to inform doctors of the results of clinical trials on the treatment of diabetic retinopathy and the application of these findings to clinical practice.

Another major public education effort in which the NEI has played a leading role is aimed at early detection of age-related macular degeneration, also known as senile macular degeneration. After published results of an NEI-supported clinical trial demonstrated that appropriately timed laser treatment can often prevent visual loss in the most sight-threatening form of this disease (which is the leading cause of blindness in Americans 65 and over), the NEI immediately alerted all of the Nation's eye specialists and the major news media about this finding. Now sight conservaton agencies are encouraging older people to use a simple,

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at-home test that can give early warning of the rapidly developing form of macular degeneration, and thus permit laser treatment to be used in time to prevent blindness.

Also, the NEI has assisted in developing information dissemination plans for other major clinical studies as their findings have become available. For example, the NEI participated in the development of such a plan for the Ocular Histoplasmosis Study, a 22-center trial that showed laser treatment can prevent blindness from an eye disorder associated with a common fungal infection.

To reach a greater portion of the public, and maximize the impact of its public information efforts, the NEI cooperates extensively with private voluntary organizations which share its interest in the prevention of serious eye disease and blindness. Among the organizations with which the NEI has collaborated in the production or distribution of information materials are the Juvenile Diabetes Foundation, the American Diabetes Association, the American Academy of Ophthalmology, the American Association of Diabetes Educators, Vision Foundation, Information for the Partially Sighted, and the Lions Clubs International.

RESEARCH TRAINING

Question: I note that there has been a change in the proportion between institutional and individual training awards. Can you explain the differences between the two types of awards, and is there any significance in making that change?

Answer: The T32 institutional training awards made by the NEI provide the resources for establishing and maintaining environments in which predoctoral and postdoctoral trainees are enrolled in formal, multidisciplinary programs of research training which emphasize relevant clinical and basic research areas of interest to the NEI. Trainees are selected and appointed to the training grant by the program director at the institution receiving the award.

Also under the National Research Service Award (NRSA) mechanism, the NEI makes individual awards to postdoctoral individual applicants for specified research training proposals. Proposals are competitively reviewed and awarded on the basis of relevance to the NEI mission and priority ranking.

The NEI decided to shift its allocation of research training funds from an earlier ratio of 75 percent institutional to 25 percent individual, and instead adopt a 50:50 allocation. The change was made because our evidence indicates that trainees supported under the individual award mechanism are more likely to remain in biomedical research and/or teaching, thus fulfilling the goal of the NRSA training awards.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

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Answer: The NIH Director, through the Director's Advisory Committee, is examining alternatives such as longer award periods, abbreviated applications, and simplification of post-award administration. Some of these or similar steps, if approved at the NIH level, can reduce administrative burdens for both the NIH and its awardees.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: The NEI, through its own staff and committee structures and those of the NIH, is constantly exploring various ways to improve administrative efficiency. Some solutions can be implemented at the institute level and some are dependent on policy decisions at the NIH level.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: The NEI consistently examines the reviewers' rationale for determining the length of awards and extends some awards when appropriate. Attention to this and other review recommendations has reduced administrative procedures for both NEI staff and applicants. NEI is also participating in the PHS Institutional Prior Approval System experiment to reduce post-award administrative costs through the delegation of certain authorities to the grantee institution.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: The NEI has expedited review for applicants for small grants for pilot projects and reduced the application-notification process to four months, a considerable savings in time. We have recently received approval to conduct a similarly expedited review of fellowship applications, and here again we will be able to offer a timely response according to criteria that are specific to the particular applications. Every effort is made to review other applications, such as those for clinical trials, as quickly as possible. High quality peer review is maintained by ensuring that the members of the review groups have appropriate expertise, and if not, that ad hoc or outside opinions are solicited. Specific measures that have been adopted include: (1) the revision of guidelines for various programs and their dissemination to reviewers and applicants, (2) the rescheduling of review cycles for core grants and training grants to allow all applications to be considered by the same review groups (to the extent possible) in the same cycle, and (3) increasing the breadth of scientific expertise on our chartered review group.

ADMINISTRATIVE BUDGET

Question: Your request for intramural research support in FY 1986 is for $14,859,000, a decrease of almost $1 million from the FY 1985 level. You indicate that the million dollars will be taken from administrative items. Please provide the Committee with a

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side-by-side itemized breakdown of your FY 1985 and FY 1986 administrative budgets, along with an analysis of the impact of this cut.

Answer: The amount requested for the NEI Intramural Research Program in FY 1986 represents a reduction of $973,000 below the amount allocated to that Program in FY 1985. The reduction reflects the Institute's judgement regarding research priorities -- some of these funds have been redirected from low priorities into higher priority areas -- and a reduction in administrative overhead. It is estimated that scaled-down efforts in low priority areas would permit a reduction of $200,000 in administrative costs. Other savings would result from reduced support services and the 5 percent pay cut.

Questions Submitted by Senator William Proxmire

FUNDING STRATEGIES

Question: Dr. Kupfer, last year in a response for the record you explained that you funded a higher percetage of your individual research project grant awards than other Institutes because you did not devote any resources to the large multi-project grants favored by some other Institutes. You said your approach gave you the flexibility to respond to new research opportunities and improved cost-effectiveness. Although you made it clear that this strategy might not be appropriate for other institutes, has there ever been a cross-Institute examination of funding strategies which would enable some Institutes to learn from the success of others?

Answer: No, there has not been a formal examination of this issue. But, discussions of funding strategies are very common amongst many groups at the NIH. There is an ongoing learning experience as each institute seeks to use and develop those funding mechanisms that best serve its particular research needs.

1984 COMPETING GRANT ESTIMATES

Question: Last year's justifications indicated you would be awarding 161 new grants and 126 renewal grants in fiscal year 1984. You actually ended up awarding only 143 new grants and 164 renewal grants--more or less a reversal of your initial estimate. What caused this shift?

Answer: The original estimates of the number of renewal and new grants that would be awarded in 1984 was based on actual experience in 1983 and the ratio of renewal and new awards as of the time the estimates were developed. At the time the estimate was made, less than one-third of the 1984 applications had been submitted and reviewed. The final number of awards and the actual proportion of renewal versus new grants reflects the fact that when all grants eligible in 1984 were considered, proportionally more high-quality grants emerged in the group eligible for renewal than in those being considered for initial funding.

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1984 RESEARCH TRAINING ESTIMATES

Question: Last year at this time you had no plans to fund competing institutional training awards in 1984. However you ultimately decided to make 13 such awards. Can you tell us why you changed your plans?

Answer: In 1983 the National Advisory Eye Council (NAEC) recommended that the NEI training budget be distributed equally between individual fellowships and institutional training grants. New training grant guidelines were also developed. Formerly, 75 percent of these funds were spent for institutional awards. To implement that recommendation as quickly as possible, plans were made to support no competing institutional training grants in 1984 and to implement the new guidelines in 1985. Later in the year, when all competing fellowships had been considered, it was decided that it would be advantageous for our training program to award three competing institutional training grants in 1984. One of the awards supported an ongoing training grant in which we did not want to lose momentum. The other two were new awards that we wanted to get under way as quickly as possible. These three training grants support 13 full-time training positions.

RESEARCH CAREER ESTIMATES

Question: According to last year's justifications you planned to make 19 awards under your research career program in fiscal year 1984 at a cost of $820,000. You actually awarded 17 grants at a cost of $685,000. The average size of each grant dropped from an estimated $43,000 to an actual $40,000. Why were your estimates so wide of the mark?

Answer: The NEI research career program includes two funding mechanisms, the research career award (K04) which supports young scientists, and the physician scientist award (K11) for newly trained clinicians. Both of these awards provide salary support for the investigator, but the salary level for the clinical scientist is somewhat higher. The 1984 estimates in last year's budget request were based on our making four or five physician scientists awards as part of our efforts to stress and enhance clinical research and research career development. We were unable to make all of those award as estimated because we received fewer K11 applications than anticipated. Therefore, the average cost of research career awards was lower than anticipated.

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NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

STATEMENT OF DR. DAVID P. RALL, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

CHARLES E. LEASURE, JR., EXECUTIVE OFFICER, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator WEICKER. Next we will hear from Dr. David Rall, Director of the National Institute of Environmental Health Sciences. This Institute's mission is to expand our understanding of how human health is adversely affected by the environment.

The Institute's budget for fiscal year 1986 is for $182.6 million, which is $12 million below the fiscal year 1985 appropriated level. I welcome Dr. Rall. Please begin. This is the Institute that is not in Washington, DC, is that correct?

Dr. RALL. That is correct.

OPENING REMARKS

We like to think of North Carolina as a particularly nice location. It is a pleasure to be here.

Let me introduce on my left our Executive Officer, Charles Leasure. I am pleased to briefly describe some of the accomplishments of NIEHS in 1984 and plans for 1985. As these budget materials were being put together, we all learned about the chemical disaster in Bhopal. In a single release of a toxic agent, well over 2,000 people were killed, and an unknown many thousands more were injured. The chemical was methyl isocyanate, which is virtually a household word now.

METHYL ISOCYANATE

MIC has long been known as a highly toxic, irritating compound. Inhalation of 20 parts per million and 60 milligrams per cubic meter is fatal quite rapidly to most people. The damage is by direct irritation. It damages the interior linings of the lungs, the eyes, and so forth. The people who died acutely died primarily of lung disease. Because of this acute toxicity and because MIC was an intermediate, that is, it wasn't in a consumer product, it was in the process of making a widely used pesticide, the toxicity had never been studied in animals to any significant

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degree. After discussing the issue within the Department, we began working with Union Carbide to perform some studies of our own so that we had some idea of what happened after an acute exposure to MIC, what the long-term consequences were.

If we expose rodents, we can get an answer in a lifetime study of 2 years or less. The similar effects in humans exposed in Bhopal would certainly take more years than that.

Further, the opportunity exists for a similar accident or incident possibly in the United States and certainly in places other than India. So we have within the last 2 or 3 weeks initiated a study of exposing mice and rats to nonlethal but high doses of MIC for brief periods of time, and we will follow these animals.

We have a few mutagenesis studies which had been negative and we have other studies which are ongoing. We talked around this table about our centers. Our center at NYU is in the process of looking for DNA damage after MIC inhalation and will also, in collaboration with us, perform some long-term studies. And the hope is that this may help us provide information that will help the victims of this toxic event.

TAIWAN PCB POISONING

Let me briefly mention one or two other areas. Another toxic release occurred in 1979 in Taiwan, polychlorinated biphenyls, which have often been mentioned by me. They were very useful compounds that are now essentially phased out, except there are still many hundreds of tons in the environment, and they will be with us for a long time.

In Taiwan, rice cooking oil, which is a staple of the diet, was contaminated by a mixture of PCB's and other contaminants and about 2,000 people were affected. Toxic effect of severe acneneuritis, neuropathy, and some bronchial problems are what we are seeing. A number of children were born of parents exposed to PCB. Those babies, incidentally, had low birth weight, about 10 percent lower than normal, and they are not growing very well. They have a lot of pigmentation and they have respiratory diseases.

We have many of the placentas from these mothers and now for the first time we are able to measure accurately the level of the contaminants of the PCB's, the various kind of PCB's and various contaminants of PCB's. We are able to determine how human tissue metabolizes and handles this very toxic compound. Although production has been ceased, we all contain about five parts per million of these agents in our blood right now.

NUCLEAR MAGNETIC RESONANCE

A couple of other interesting studies in closing, we are developing techniques of nuclear magnetic resonance, a very fancy way of looking at molecular activity to create images of various body tissues without invading the animal or without even having to anesthetize the animal. We can get pictures of the liver of rats while they are still alive; we can determine benign and malignant tumors within the liver and we can iden-

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tify certain types of liver diseasas as differentiated from tumors or cancer. This is the first time that we can look at the development of toxicological processes within living animals and this could truly revolutionize animal toxicology.

ONCOGENES

You have heard from a number of people about oncogenes, bits and pieces of DNA which seem to be activated as an early step in the process of developing cancer. Using our animals which have been exposed to various carcinogens, we are looking for the activation of oncogenes in normal liver and benign tumors and malignant tumors. These studies are too early to have any firm results. But I think this will be terribly exciting and begin to tell us much more about each study than we were able to determine before.

I am pleased to have presented these brief highlights and I will be delighted to answer any questions.

PREPARED STATEMENT

Senator WEICKER. Thank you, Dr. Rall. We will place your statement in the record and then proceed to some questions.

[The statement follows:]

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STATEMENT OF DR. DAVID P. RALL

Mr. Chairman and Members of the Committee, I am pleased to be with you today to tell you about some of the important research projects being supported or conducted at the National Institute of Environmental Health Sciences (NIEHS) in Research Triangle Park, N.C.

NIEHS was established in 1966 to provide a center within the Federal government to conduct biomedical research on the effects of environmental agents on human health. The creation of the Institute was a response to an emerging change in the Nation's critical health needs from acute, communicable diseases such as pneumonia, tuberculosis, and influenza--diseases caused by infectious agents for which therapeutic and preventive measures were available, to the problems of chronic diseases such as cancer, heart disease, birth defects--diseases of a largely uncertain origin.

At NIEHS, we investigate the effects of environmental agents on human health through a carefully structured research program within the Public Health Service and the National Institutes of Health. The aim of the research is to develop knowledge needed to understand and prevent environmentally-caused health effects.

We bring together scientists from related scientific disciplines to conduct both basic research--research aimed at developing a fundamental understanding of biological processes or disease mechanisms--and applied research--research which looks at immediate toxicological problems and is focused on specific public health issues.

NIEHS research is carried out through four programs; the Extramural Program (EP), the Intramural Research Program (IRP), the Biometry and Risk Assessment Program (BRAP), and the Toxicology Research and Testing Program (TRTP). TRTP provides most of the resources for the National Toxicology Program (NTP).

The tragic event unfolding in Bhopal, India illustrates the need for the research information NIEHS generates. With an exposed population of close to a quarter of a million, and deaths estimated in excess of 2,000 people, the Bhopal disaster is one of the worst chemical disasters in history. An editorial in Chemical and Engineering News said that "the disaster seems to be an accident that just could not happen." But it did.

The gas which escaped from the plant, methyl isocyanate, is mucous membranes and is especially toxic to the respiratory tract. With exposure levels as high as they were at Bhopal, the victims literally drowned in their own fluids.

We could predict the immediate effects of a release of that much methyl isocyanate into the 25 square mile radius in India. However, we do not know what will happen to the people of Bhopal 1, 10, 20, 30, or 40 years from now as a result of this exposure.

A search of the literature revealed no epidemiological data, no data on carcinogenesis, on teratology, or on metabolism--data that are critical in predicting the eventual fate of those exposed.

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The NTP conducted a short-term Salmonella test to determine if methyl isocyanate causes cellular mutations, and the test was negative. Methyl isocyanate is now undergoing more extensive testing in animals by the NTP to determine what the long-term effects are from an acute exposure.

It is not surprising that so little is known about a chemical such as methyl isocynate, even though it is produced in large quantities to make commonly used pesticides like Sevin and Temik. A National Academy of Sciences study titled Toxicity Testing: Strategies to Determine Needs and Priorities, released in 1984, looked at a specially selected subset of a universe of 63,798 chemicals and determined that "...of the tens of thousands of commercially important chemicals, only a few have been subjected to extensive toxicity testing and most have scarcely been tested at all."

The current method for determining whether chemicals will cause adverse chronic health effects involves long-term administration to several hundred test animals, usually rats and mice. These tests are expensive, often costing more than half a million dollars.

There has been continuing disagreement about the utility of animal studies for determining human health hazards. However, recently two prestigious groups examined and endorsed the continued use of animal studies in toxicology.

The White House' Office of Science and Technology Policy (OSTP) released a preliminary draft of its report in May 1984. Three months later, the second report was issued by the NTP's Ad Hoc Panel on Chemical Carcinogenesis Testing and Evaluation. The panel consisted of experts on carcinogenesis from industry, academia, and public interest groups. The NTP report is technical, a state-of-the-art document for toxicologists, while the OSTP report is oriented toward application of animal studies under existing environmental laws. But significantly, both reports endorse the relevance of animal studies to gather essential data on chemical carcinogenicity.

The National Toxicology Program is the principal mechanism for carrying out such long-term animal studies within the Federal government. Of the 15 studies of chemicals which were peer reviewed in FY 1984, there were three which I would like to mention here:

Intermediate range chrysotile asbestos (the type found in nature), given orally in the diet at the one percent level, caused benign intestinal polyps in rats. While we have long known inhaled asbestos causes tumors, this is the first study to show a similar effect from asbestos administered orally. However, similar studies with short fiber asbestos--the type found in water supplied through asbestos pipe--and other types (amosite and crocidolite) did not show an effect after oral administration. Also, similar studies of two types of crysotile and amosite were negative in hamsters.

A study of 1,3 butadiene, a chemical used extensively to make artificial rubber, provided clear evidence of carcinogenicity in mice at several test concentrations near the Threshold Limit Value established by the Occupational Safety and Health Administration.

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These tumors were uncommon and occurred at an earlier age than found in most studies.

A widely-used soil fumigant, suggested as the replacement for EDB, Telone II, was carcinogenic, causing tumors of the urinary bladder, stomach, and lungs in mice, and stomach and liver in rats.

In addition to conducting conventional testing, using methods that are constantly being refined to produce more and better information, the NTP is in the forefront of the effort to develop newer, faster, less expensive ways to determine whether chemicals are hazardous.

This effort--to which we are devoting $10 million a year--is needed to help us select better test methods and evaluate results from long-term studies and, in the long run, to reduce the need for long-term animal studies.

However, before this goal can be acheived, the Program must first be able to assure the reproducibility of test results, their accuracy in predicting toxic effects, and establish a clear relationship between the in vitro, or short-term test, and toxic effects in vivo, in animal tests. To do this, in FY 1984 the NTP conducted 396 short-term tests, broadening our knowledge base of short-term tests.

Other investigators in NIEHS are using laboratory approaches to enhance our ability to evaluate quantitatively the consequences of human exposure to chemicals. This approach should contribute to establishing quantitative risk assessment in humans. An example of this effort is a study of a 1979 incident in Taiwan in which rice oil, a dietary staple in that country, was contaminated by polychlorinated biphenyls (PCBs) over a 9 month period. This insidious exposure caused dramatic dermatological changes, including severe acne, discolored and deformed nails, hyperpigmented gums, and swollen eyelids. Poisoned women produced low birth weight children, some of whom were affected with similar signs and symptoms. In general these changes gradually lessened over time.

Little is known about how PCBs and their contaminates induce such toxic effects, but in experimental animals these agents cause marked increases in levels of enzymes that metabolize drugs and chemicals. To study the possibility that similar changes can occur in humans, NIEHS scientists measured levels of several of these enzymes in placental tissue obtained from women who were exposed to PCB and who gave birth during 1983 and 1984. The activity of enzymes in the placental specimens from the exposed women was substantially elevated, typically several hundred fold over activity measured in placental specimens from unexposed Chinese women. This study demonstrated that exposure to chemicals such as PCBs, which are widespread environmental contaminants, can cause substantial and persistent effects on human metabolism. Such changes may not only be important in themselves, but may also alter the body's response to drugs or other foreign chemicals.

I have given some examples of how we have conducted evaluations of toxic chemicals that are relevant to public health issues. We also support fundamental research that increases knowledge of how chemicals cause cell damage and alter biological processes. This

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is a major objective of our research support both in our Intramural Programs at NIEHS and through grants to Centers and to individual investigators in universities.

As knowledge of modern biology continues to develop at a surprisingly rapid pace, the gap between basic and applied research narrows. In recent appearances before your Committee, I have talked about the way that molecular genetics and recombinant DNA technology have expanded our knowledge of chemically caused mutations in cells. These findings have led to new techniques and understandings that are now being applied to evaluations of toxic chemicals.

A new technology we are now using to study toxic chemicals is nuclear magnetic resonance spectroscopy. In the Intramural Program, high magnetic field spectroscopy [nuclear magnetic resonance (NMR)] has been employed in animals through the use of surface coils to trace metabolic changes in phospho-organic compounds which reflect toxic chemical damage to the liver. In these non-invasive studies using live animals, we generate NMR images based on the hydrogen resonances in water which, in some cases, can distinguish tumor tissue from fat infiltrations in the liver. The application of NMR spectroscopy and imaging to animal toxicity studies is just beginning, but a rapid development of this technology is expected.

One of the ways in which NIEHS assists in supporting high quality biomedical research is through its grants to nine Environmental Health Sciences Centers and three Marine Centers in the Nation's universities. I would like to mention a few of the projects we are supporting:

At the Harvard School of Public Health, a short term in vivo animal test has been developed which predicts whether chemicals can cause emphysema, fibrosis, or chronic bronchitis. Studies using the system have shown that volcanic ash is relatively non-toxic. But the system showed that the combustion byproduct of automobile waste oil--proposed for use in kerosene-type home heaters--is highly toxic.

At the University of Rochester scientists are using a technique to measure mercury in hair which allows them to monitor previous exposure to this highly toxic metal. Knowing that hair grows a centimeter a month, they are able to identify periods of excess exposure to this metal by measuring mercury levels in hair. Applying this technique to hair from pregnant women in a population from a polluted area of Northern Ontario, it has been determined that minor neurological impairments occur in newborns from levels of maternal mercury exposure equivalent to about 100 times normal exposure levels.

The University of California at Berkeley has assembled a large computerized data base which includes the results of long-term animal cancer studies conducted by the National Cancer Institute and the NTP through July 1981 and related studies from the scientific literature. Data and information from approximately 3,000 single sex, single species experiments involving 770 different compounds are contained in the Data Base. Included is information on dose levels, length of exposure, histopathology,

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tumor incidence, a carcinogenicity potency index and its related statistical significance and the author's judgment as to carcinogenicity of the compound. The data are presented in a format that allows for comparisons among chemicals, species, target organs and other variables of interest.

Putting all this information into a single data base will permit scientists to evaluate and draw conclusions about results of these studies. Later this month, the data base will be published in the NIEHS journal, Environmental Health Perspectives.

I am pleased to tell you that the report of the Third Task Force on Human Health and the Environment has been submitted to the Committee. The 1983 House Appropriations Committee Report instructed the National Advisory Environmental Health Science Council to "...assess the state of existing knowledge to determine areas of particular promise in the environmental health sciences."

This effort, co-chaired by Dr. Arthur Upton of New York University and Dr. Bernard Goldstein of the Environmental Protection Agency, continued for over a year. It has involved many of the Nation's most respected scientists from academia, industry, and government.

The report describes an explosion of scientific technology, the use of which will allow us to learn far more about effects of chemicals at low doses on important biological systems and of previous exposures in human subjects as well as experimental animals. In addition it lays out opportunities for future research. Our staff, the National Advisory Council and other review groups are currently studying it and we expect that it will provide the basis for our planning for the next few years.

This concludes my opening statement. Mr. Chairman, the 1986 budget request for this Institute is $182,611,000, a decrease of $10,637,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. Accomplishing this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of competing research project grants and centers funded. Specifically, in 1985 this Institute will fund 88 new and competing grants of which 11 will receive three years of support. In addition, we will fund 12 centers, of which 3 will receive two years of support.

I will be happy to answer any questions.

Biography of Dr. David P. Rall

August 3, 1926. Aurora, Illinois

Education: B.S., North Central College, 1946; M.S. (Pharmacology), Northwestern University, 1948; M.D., Northwestern University School of Medicine, 1951; Ph.D. (Pharmacology), Northwestern University, 1951.

Professional History: 1952-53, Intern, Bellevue Hospital. 1953-58, Scientist, Laboratory of Chemical Pharmacology, National

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Cancer Institute. 1958-63, Head, Clinical Pharmacology and Experimental Therapeutics Service, General Medicine Branch, National Cancer Institute. 1963-69, Chief, Laboratory of Chemical Pharmacology, National Cancer Institute. 1966-71, Associate Scientific Director for Experimental Therapeutics, National Cancer Institute. 1971-present, Assistant Surgeon General, USPHS.

Professional Organizations: American Association for the Advancement of Science, American Association for Cancer Research, American Public Health Association, American Society for Clinical Investigation, American Society for Pharmacology and Experimental Therapeutics, Society for Occupational and Environmental Health, Society for Risk Analysis, Society of Toxicology.

Honors, Awards: Editorial Board, Proceedings of the Society for Experimental Biology and Medicine, 1962-65. Member, National Institutes of Health Chemotherapy Study Section, 1965-67. PHS Meritorious Service Medal, 1966. Chairman, National Institute of General Medical Science Pharmacology Toxicology Review Committee, 1967-69. Editorial Board, Pharmacological Reviews, 1969-72. Chairman, DHEW Departmental Committee on Drug Research and Regulations, 1970. Associate Editor, Cancer Research, 1970-74. Chairman, OST-CEQ Ad Hoc Committee on Environmental Health Research, 1971-72. Adjunct Professor, University of North Carolina, Chapel Hill, 1972-present. US Coordinator, Environmental Health Program, US-USSR Health Exchange Agreement, 1972-present. Chairman, DHHS Committee to Coordinate Environmental and Related Programs, 1973-present. Editorial Board, Archives of Environmental Health, 1973-76. Associate Editor, Journal of Toxicology and Environmental Health, 1974-78. DHEW Distinguished Service Medal, 1975. Member, DHEW Secretary's Review Panel on New Drug Regulation, 1975-76. Member, NAS Safe Drinking Water Committee, 1975-1977. Chairman, Committee on Health and Environmental Effects of Increased Coal Utilization, 1977-78. Member, Institute of Medicine, 1979-present. Editorial Board, American Journal of Industrial Medicine, 1980-present. Member, WHO Programme Advisory Committee, 1980-present; Chairman, 1980-81. Editorial Board, Risk Analysis, 1981-present. Editorial Board, Regulatory Toxicology and Pharmacology, 1981-present. Arnold J. Lehman Award, Society of Toxicology, 1983. Member, US Delegation to the US-Japan Cooperative Medical Science Program Committee, 1984-present.

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CENTERS SUPPORT

Senator WEICKER. Your Institute supports 9 environmental health centers and 5 marine and freshwater biomedical centers for a total of 14. Your budget justification shows only 12 centers in your revised fiscal year 1985 and requested fiscal year 1986 budgets. Which of the nine environmental health centers and which of the five marine and freshwater biomedical centers have been closed?

Dr. RALL. None of the nine health centers were closed. The difference between the five and the three is more of a miscarriage than a closure. We had two that simply did not come in with high enough scores at the end of last fiscal year. We had anticipated they would be funded but they weren't. So instead of having five, we have three and the current policy is to maintain in 1985 what we had present in 1984.

The three marine centers are Duke, Seattle, and the University of Wisconsin at Milwaukee.

Senator WEICKER. Those centers are operational?

Dr. RALL. Yes; and have been for a number of years.

Senator WEICKER. And the remaining two?

Dr. RALL. Did not have a high enough priority to be funded last year. We have a number of applications in-house, however.

Senator WEICKER. I don't quite follow you. The two that did not have a high enough score, which ones were those?

Dr. RALL. I would prefer not to discuss individual institutions.

Senator WEICKER. These are the ones you expected to fund?

Dr. RALL. Yes.

Senator WEICKER. But then in the course of processing didn't come——

Dr. RALL [interposing]. That is right. One can never predict precisely whether applications will get high enough priority.

Senator WEICKER. I am a little bit concerned about it. Obviously there was a certain work expected to be accomplished by five centers. So anyway you look at it, that is a sizable reduction in the work expected to be accomplished regardless of the individual Institute. What has happened to that work?

Dr. RALL. I presume that some of it will simply not get done. We have been able to use some of the funds to more generously support the three marine centers that I described. So to some extent, they can take up some of the slack.

TESTING OF CHEMICALS

Senator WEICKER. This country has been producing industrial water and hazardous chemicals for generations. It has been only within the last decade or so that we have begun to understand their impact upon our environment and the health of our citizens. You have said that there are 65,000 chemicals in commercial use in the United States and only a small fraction have been adequately tested for safety.

Do you think your activity should be expanded to meet the needs as you yourself have stated?

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Dr. RALL. We have looked very carefully at the National Academy of Sciences' report that came out about the time the hearings were going on this past year. There clearly are chemicals that need to be tested. Our testing program is going on at what we think is a very proper rate. We are initiating full-scale tests on about 20 chemicals a year. We have special tests on more like 35 or 40, which are not complete studies but which may be adequate. All told we have somewhere around 400 chemicals on tests at any one time.

I think that probably is an adequate rate of testing. We are working very hard to develop more rapid and less expensive tests so that we do not have to use the enormously expensive 2-year study and two species of animals as the ultimate way of determining relative safety. If we can use much shorter tests, using fewer animals, we will be saving a lot, and that is what we are working very hard to do and with the idea that that probably can be accomplished in the next 3 or 4 years. I am comfortable with the rate that we are going right now.

Senator WEICKER. What is the 1985 and 1986 budget relative to this particular aspect?

Dr. RALL. It is about $73 million and it is about level for the 3 years.

Senator WEICKER. Senator Chiles?

RAC GUIDELINES

Senator CHILES. We are beginning to hear a lot more about biotechnology and some have called it the last scientific revolution of the 20th century, while others have called it the great scientific threat to man and his environment. The potential is significant. Certainly legitimate concerns have been raised regarding release of genetically engineered substances and organisms into the environment.

The NIH Recombinant DNA Advisory Committee [RAC] has been the leader in providing advice on biotechnology and involved guidelines that have allowed the research to go forward. Now we are seeing the biotechnology beginning to move out of the laboratory and into the marketplace.

I would like to know what your opinion of the existing RAC guidelines are and their relevance to the commercialization of biotechnology?

Dr. RALL. Senator Chiles, that really deals with areas that are beyond the purview of the National Institute of Environmental Sciences. We deal with chemicals whether they be natural or synthetic, but the process of genetic engineering and the release of new genetic material is not in our purview, and I would simply not feel comfortable to answer the question. I think perhaps Dr. Wyngaarden may.

Senator CHILES. Dr. Wyngaarden.

Dr. WYNGAARDEN. I will be happy to speak to that. The NIH Recombinant DNA Advisory Committee has been in existence since 1974 and has evolved guidelines for the conduct of recombinant DNA research. These guidelines started off to be rather stringent and from time to time were revised, usually toward less stringent requirements. The perceived risks that were discussed first at the Asilomar conference 10

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years ago were found to be probably less than had initially been anticipated. And with this has come a series of revisions of these guidelines that have enabled the work to go forward.

There are several subcommittees or working groups of the RAC that deal with specific issues. There is one on release into the environment, there is one on human gene therapy, and so forth.

The RAC, I think, has functioned very responsibly, has been widely praised here and in other countries, has received very strong support from the industrial community, and has had very little challenge until just recently when a field test was approved unanimously by the RAC but did represent the introduction of engineered organisms into the environment on a small scale test plot.

That field test has been held up, as you know, and is under more careful scrutiny.

RAC CONTINUATION

Senator CHILES. Do you envision a continuation of RAC's current role in biotechnology commercialization and safety regulations?

Dr. WYNGAARDEN. I envision the continuation of its present role of risk assessment of scientific research. The administration has proposed in the Federal Register on December 31, 1984, an expanded plan for risk assessment of biotechnology that would involve, in addition to the NIH RAC, the creation of review groups in several agencies, including the FDA, the National Science Foundation, which would deal primarily with environmental research, EPA, and the Department of Agriculture, and these five study groups would report to a parent committee composed of two members of each of these RAC's, and this overarching committee would report, according to this plan to the Assistant Secretary for Health in the Department of Health and Human Services. That is out for public comment now. Comments are coming in that will be evaluated before the next step is taken.

Senator CHILES. What was NIH's role in that effort, and what is your opinion of it?

Dr. WYNGAARDEN. We have been very active on that committee. This is a Cabinet Council group. I have met with them practically every meeting; if I was not able to, another representative from NIH was there. I feel that is a promising and valid approach to the problem of risk assessment and provides the kind of expertise within each agency that would pertain most closely to that agency's mission.

RISK ASSESSMENT RESEARCH

Senator CHILES. Obviously, the release of novel substances and organisms raises some interesting questions. Critics have continued that we don't have enough basic knowledge or sufficient data base regarding interaction of these new products in the environment to allow their release at this time. Is NIH either funding or actually doing any basic or generic risk assessment research regarding genetically engineered products and, if so, will you tell me about the research and the commitment

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in terms of manpower and funding and whether new efforts in this area will be made in the future?

Dr. WYNGAARDEN. We continue to fund a very large amount of work in recombinant DNA biotechnology. The direct funding of that work is on the order of $500 million per year. We have another billion dollars in related work that may not be precisely on recombinant DNA technology but related to that. Altogether, this portfolio amounts to about 25 percent of our activity. So, yes, we continue to fund a very large amount of work in that field and, in each case, if the experiment to be conducted falls within the range of such studies that require RAC review, then that review and NIH approval is required before the research can be done. So there is an ongoing investment in risk assessment as the research is conducted.

Senator CHILES. How does that NIH funding for the biotechnology risk assessment compare with your funding for other types of biotechnology research?

Dr. WYNGAARDEN. I would have to look more closely at that range of studies to see which ones would fall precisely in what I think you refer to in a more narrow sense as risk assessments, and I will be happy to do that for the record.

Senator CHILES. Thank you.

Dr. WYNGAARDEN. I can't give you those figures at this moment.

[CLERK'S NOTE.—NIH subsequently informed the subcommittee that such figures are not available.]

Senator CHILES. I would appreciate it if you would.

REGULATION OF BIOTECHNOLOGY

In your opinion, do we know enough about the basic risk elements of biotechnology to develop a good regulatory framework?

Dr. WYNGAARDEN. Yes; I think we do. In connection with the specific proposed field test of the ice-minus bacteria, that has now been reviewed by the RAC on two occasions. We did recently prepare a detailed environmental assessment concerning that proposed field test and came to the same conclusion that there was no significant risk in that particular study. Ice-minus bacteria exist in nature all around us and the ability to increase the concentration of them locally at a critical time of the year might have a very appreciable effect on crop damage from frost.

We see that as a potential step of enormous benefit potentially to citrus crops and others, and from our standpoint allowing the proposed field test by the University of California poses no significant risk.

BIOTECHNOLOGY PRODUCT RISK

Senator CHILES. In your opinion, what is an acceptable level of risk for the release of biotechnology products? Can we put a number on it in a manner similar to the way we assess financial risk, for example?

Dr. WYNGAARDEN. Well, I couldn't do it on short order. That particular field test, as I have indicated, we think it entails no significant

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risk. I think this is not a zero risk society and we have to make those decisions.

Senator CHILES. I understand.

Dr. WYNGAARDEN. If the risks are small, in many cases is it worth the potential gain. That is of course a judgment call to be made on all such proposed experiments.

Senator CHILES. Are some types of genetic engineered substances inherently more risky than others?

Dr. WYNGAARDEN. Oh, I would have no doubt that would be the case, yes.

Senator CHILES. I have a few other questions along that area I would like to submit for the record.

INFANT MORTALITY

I wanted to ask you, Doctor, a few questions about infant mortality. We have made great strides in recent years in prolonging life. We see that life expectancy for men and women continues to climb and from what we know about lifestyles we can improve health and people can expect both the quantity and quality of their life to increase. With that happening, it makes it particularly disturbing to see that we rank 17th in the world in infant mortality, far behind other developed nations.

I wonder if you would briefly review for us what research supported by the National Institutes of Health is focused on infant mortality and its chief cause, low birth weight?

Dr. WYNGAARDEN. With your permission, I would like to ask Dr. Alexander to respond to that.

Senator WEICKER. Let me try to keep an order on this hearing. I have further questions as do other members of the committee for Dr. Rall. Otherwise, he can stand down now, and what we will do is have Dr. Alexander come back up here and respond to any questions the Senator from Florida may have. Thank you.

Dr. RALL. Thank you very much.

Senator WEICKER. I might add I am delighted to have the Senator from Florida ask questions in this area. It is one that I feel is one of the most important problems confronting the Nation. I do not think the administration requests are adequate to meet the challenge, and the more emphasis on it by the U.S. Senate the better, as far as I am concerned.

Go right ahead.

Senator CHILES. Mr. Chairman, I hate to be going over the same ground. I know of your interest in this area and Senator Proxmire's as well. It is an area of great interest to me.

Doctor, could you briefly review for us what research is supported by NIH's focus on infant mortality and its causes, low birth weight?

Dr. ALEXANDER. We have focused our efforts in the National Institute of Child Health and Human Development on the problem of low birth weight. Right now low birth weight is the most important factor in infant mortality in this country. In fact, at any birth weight below 3,000

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grams our infants survive better than those in any other country. Our problem is that we have more low birth weight babies, 6.8 percent of all children born in this country weigh less than 2,500 grams. Two-thirds of all infant deaths occur among low weight infants.

Our infant mortality has been declining very rapidly, in fact, cut in half over the past 20 years, but we may be reaching the limits of what we can do at the present time given our low birth weight situation. Most of our improvements in infant mortality in the past 10 years have occurred as a consequence of our ability to save more and more of these low birth weight babies, but the rate of low birth weight is not declining appreciably. The NICHD proposed a special increased effort beginning last year in research directed toward reducing the incidence of low birth weight.

In the opening statement that is in the record I outlined our efforts in this area. These efforts include clinical trials trying to address the problems of maternal infections and nutrition as contributing factors in infant low birth weight; epidemiologic studies of factors that are associated with risk for low birth weight; and a new center that we will be establishing this year focusing on intrauterine growth retardation research, trying to get at this aspect of low birth weight prevention. In fiscal year 1986, we plan to fund a new system of networks of maternal/fetal medicine units in obstetrics looking at high risk pregnancies, trying to identify women who are at risk for having a low birth weight infant and develop new and improved ways of treating those women during pregnancy to try to reduce their chances of having a low birth weight infant.

In addition to a wide range of activities focused primarily on low birth weight the Institute supports research on complications of pregnancy that lead to infant mortality and, in the newborn area, a number of studies directed at disorders of newborns—necrotizing enterocolitis, respiratory distress syndrome, and causes of infant mortality in the newborn period.

SUDDEN INFANT DEATH SYNDROME

Senator CHILES. Are we making any progress in finding the cause of sudden infant death syndrome [SIDS]?

Dr. ALEXANDER. We have identified a number of factors that are associated with sudden indant death syndrome. These include many of the same things associated with low birth weight: teenage pregnancy, unmarried mothers, smoking in pregnancy, low economic status, and many other factors. We have identified some things that are not responsible for sudden infant death syndrome. For example, DPT immunization shows no relationship to SIDS. We have not yet come up with a cause. Right now, our research is focused on neurocontrol of cardiorespiratory mechanisms and trying to get at the issue of whether there is a maturation lag in this control that may be responsible for the sudden infant death syndrome. We don't have an answer yet. We are still working.

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INFANT MORTALITY WORK GROUP

Senator CHILES. I understand there is a task force or working group within HHS, and I believe another in NIH, to focus on infant mortality. What has it become?

Dr. ALEXANDER. There are two task forces. One, the low birth weight prevention work group was established by the Assistant Secretary for Health and is focusing on low birth weight as a major factor in infant mortality. This group has reviewed our changing picture in infant mortality and low birth weight and developed specific efforts to help the States in assessing what is happening in their particular region in terms of low birth weight and infant mortality. This is primarily under the direction of the Division of Maternal and Child Health in the Health Resources and Services Administration.

One specific action being initiated by the work group is to form teams of experts to provide assistance to the States to conduct actual infant mortality reviews, case by case, within the State. These reviews will try to identify causative factors in each case and determine whether there are preventable deaths and recommend what kind of specific intervention might be made at the State level to prevent deaths from such causes in the future. The second group is the infant mortality subcommittee of the task force on black and minority health established by the Secretary. That group will be presenting its report and recommendations to the Secretary in June.

Senator CHILES. What would you recommend as the best way to get a coordinated effort going to tackle the national problem? The Institute of Medicine has recommended a commission be created to study and design a comprehensive approach to it.

Dr. ALEXANDER. I think there are two things we need to do and these are emphasized by the Institute of Medicine report. One is to apply what we know. If we applied what we know, we could make a significant impact on both low birth weight and infant mortality. But even if we did all this, there would still remain a substantial nucleus of infant mortality and low birth weight that we can't explain or prevent by methods we know now.

So the second component of our effort has to be a research effort, and this is the work that we are supporting and that we are proposing in our low birth weight initiative. I think these two components go hand in hand, and if we are to make a significant impact on infant mortality and low birth weight, both have to be done.

Senator WEICKER. If the Senator would yield, I also will add the administration has proposed substantial cuts in the community health services centers. Of course, that is where a good portion of the advice on prenatal care takes place.

POVERTY AND LOW BIRTH WEIGHT

Senator CHILES. It is my understanding, Mr. Chairman, an awful lot of low birth weight has to do with poverty, has to do with these pregnant mothers simply not getting enough nutrition to deal with it. The

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studies pretty well indicate, do they not, with the Women and Infants Feeding Program that we have had much lower incidence of low birth weight where women are involved in WIC programs, does it not?

Dr. ALEXANDER. The studies that have been conducted in the WIC Program do indicate that participants in the program have a lower incidence of low birth weight infants than in comparable control groups.

Senator CHILES. Considerably improved.

Dr. ALEXANDER. Improved. I'm not sure I would say considerably, but certainly improved.

Senator CHILES. Well, if the studies indicate that, would it make sense that we would have a policy that would actually cut people off of that program? One hundred forty thousand people will be cut off that program, according to the CBO figures, if we have a freeze in the WIC Feeding Program.

Dr. ALEXANDER. There is no question but that supplemental feeding programs for women who have nutritionally inadequate diets do reduce the incidence of low birth weight.

Senator WEICKER. If I can, just to follow up again here, the Community Health Center requested funding for 1985 is $375 million and the 1986 request is for $360 million. Community health centers are the ones on the first line, if you will, giving out prenatal care, advice, et cetera. The maternal and child health block grant, the maternal child health block grant is frozen at $478 million—$478 million. Obviously the population is increasing, so we can only surmise there will be less services in that area. Here are your two key components that relate to the problem you raise. One cut; one frozen. I think the statistics alone on infant mortality are a disgrace to the Nation.

TREATMENT COSTS OF LOW BIRTH WEIGHT INFANTS

Senator CHILES. I understand a Harvard study showed pregnant women who received nutrition supplementation through the federally funded WIC Program had a lower birth weight of 3.4 percent while a comparable group of nonparticipants had 14.6 percent. Pretty drastic change.

Doctor, can you tell me, does it cost less money to treat a low birth weight baby after he has been born or to prevent one from happening through a WIC Program?

Dr. ALEXANDER. It is very clear that prevention is highly cost effective. Our cost for neonatal intensive care alone for low birth weight infants in this country run around $2 billion a year. The Institute of Medicine report came up with a figure of $3.38 saved for every $1 invested in prenatal care.

Senator CHILES. So if it is costing us $2 billion a year now on low birth weight babies, it would seem to be a pretty good investment to reduce that low birth weight at the outset, would it not?

Dr. ALEXANDER. Yes, sir.

Senator CHILES. Isn't the average cost somewhere from in the neonatal care—it's a terrific figure.

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Dr. ALEXANDER. It's about $1,000 a day.

Senator CHILES. $20,000 to $100,000 per infant.

Dr. ALEXANDER. That's a range, and it can be higher than $100,000 for a long and complicated course.

Senator CHILES. That is a startling figure.

Is there any coordinated effort throughout HHS or with the Agriculture Department to deal with these poverty and hunger aspects of infant mortality?

Dr. ALEXANDER. There certainly is an effort within the Department, and our efforts are coordinated with the Agriculture Department to deal with this whole problem of infant mortality. The Department is increasingly focusing its attention on the problem of low birth weight and infant mortality. Secretary Heckler has designated this as a major concern of hers and one that will receive increasing attention in the ensuing months.

Senator CHILES. Thank you, Mr. Chairman.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much, Senator Chiles.

There will be some additional questions submitted for your response.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

HEALTH SCREENING AND DISEASE REGISTRIES

Question: I understand that NIEHS has conducted a large health screening study involving hundreds of residents of North Carolina. Please describe the status of this study and tell us of your findings.

Answer: NIEHS is not conducting any primary health screening studies. There is, however, an ongoing study that involves periodic examination of children. NIEHS is studying the effects of contaminants of breast milk on the health of breast-fed children. The particular contaminants of interest are the industrial chemicals PCBs (polychlorinated biphenyls) and the pesticide DDT. Approximately 900 volunteer women enrolled at three centers in North Carolina between 1978 and 1982. Their children are being followed from birth to age 5 years. Breast milk, blood and placenta were collected from the mother and analyzed chemically to determine the amounts of these contaminants which were present. In order to determine whether there are any harmful effects attributable to these contaminants, the progress of the children is being checked by periodically questioning the mothers and examining the children. Because the study is ongoing, there are only limited findings as yet. The chemical analyses have all been performed, with the expected result that all of the women have these chemicals present at low levels. However, there is no information as yet on whether the health of the children is affected.

Question: Are there any plans at NIEHS to conduct a national health screening study?

Answer: At present there are no plans to expand the breast milk study or to conduct other studies involving health screening.

REACTION TO HAZARDS

Question: Specific environmental hazards to human health can literally explode into our lives at any moment. What research mechanisms does your Institute have in place that can respond to environmental emergencies?

Answer: The NIEHS does not perform on-site investigations of environmental emergencies. We do, however, conduct tests of suspected hazardous materials through our Toxicology Research and Testing Program and provide the results to those agencies charged with taking regulatory or other public health actions. We are, for example, currently testing MIC, the material that caused the recent catastrophe in India.

Question: How is institutional support of on-going intramural projects protected from reprogramming of funding or transfer of personnel as emergencies demand your attention?

Answer: It is not so much a question of reprogramming or reassignment as it is one of readjusting priorities. Some projects may be delayed or reduced in scale temporarily when required. In general, these kind of problems are handled in the National

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Toxicology Program where we can redirect work being done under contract and therefore do not have to transfer Institute staff.

GENETIC SCREENING

Question: Has NIEHS performed or supported research in trying to determine the frequency of genetic mutations in humans?

Answer: NIEHS has not performed research on the background frequency of genetic mutations in humans. All such studies at NIEHS are conducted using the laboratory mouse as a model system. However, we feel it is reasonable to expect that a chemical which induces mutations in mouse germ cells also has the potential to induce mutations in human germ cells. It is, however, recognized that important factors such as metabolism and distribution differ among mammalian species and that these factors may influence the germ cell mutagenicity of any given chemical.

Question: Has NIEHS performed or supported research on the general topic of genetic screening?

Answer: Using the mouse as the study organism, such research and testing is supported by NIEHS. In general, parental mice are exposed to known or suspected mutagens and then bred. Their offspring are then screened for evidence of newly induced mutations observed as morphological variants (e.g., coat color) or electrophoretic variants (e.g., altered blood proteins). The ultimate purpose of the studies is to identify the chemicals which may pose a genetic risk and to provide a portion of the data that is needed to derive estimates of human genetic risk.

SUPERFUND

Question: The Superfund has been set up to deal with environmental emergencies. In the event of an emergency are you eligible for Superfund money?

Answer: Mr. Chairman, we are eligible to utilize Superfund money through two different mechanisms.

Under an agreement between the Environmental Protection Agency and the Public Health Service, funds are transferred to the Public Health Service to carry out a variety of health related responsibilities. Among these are toxicology testing activities to be carried out by the National Toxicology Program (NTP). Under this agreement for the past several years the NTP has been conducting tests of chemicals nominated for testing by the EPA.

In addition, EPA can call on the NTP for assistance on a case by case basis. An example of this was when the EPA asked NTP to undertake the testing of dioxin contaminated dirt from Times Beach, Missouri to determine whether the dioxin in that dirt was biologically available and thereby could pose a threat to human health. In that case, the Institute paid for the testing. However, the mechanism is available for NTP to conduct such testing when requested by EPA and to be reimbursed by the EPA.

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PREVENTIVE RESEARCH

Question: In a speech before the American Pharmaceutical Association Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: The research objectives of the National Institute of Environmental Health Sciences (NIEHS) are largely preventive in nature. This includes the basic research programs as well as the chemical testing program. The latter program is designed to identify those chemicals that may under some circumstances cause cancer and other illnesses in exposed human populations.

During FY 1984 NIEHS' testing component (i.e., the NIEHS activities dedicated to the National Toxicology Program) reported out 13 chemicals studied for their potential to produce cancer in laboratory animals, with a high probability that these same chemicals could cause cancer in humans. Of those chemicals, 8 have been found to be carcinogenic in some species of animals. Among them are 1,3-butadiene, a common industrial chemical in the rubber industry, and benzene which ranks fifth among organic chemicals produced in the United States. It must be noted that more than 50 percent of the chemicals studied by NIEHS/NTP during the past year were found not to have any potential for adverse health effects.

An important study reported by the NIEHS/NTP in FY 1984 was the investigation of the hazard of ingesting asbestos in drinking water and food. Short-length crysotile asbestos fibers, the type found in water from asbestos cement pipe, when fed to rats showed no evidence of carcinogenicity. In contrast, longer length crysotile fibers, similar to those found in insulation, caused benign intestinal polyps in a small percent of male rats. Two other types of asbestos, amosite and crocidolite, showed no evidence of carcinogenicity under similar exposure conditions. The importance of this finding is that while these types of asbestos are known cancer-causing materials when inhaled, the health hazard when ingested is unknown. These studies demonstrate that asbestos when ingested may pose a health hazard but that fiber type and length are important parameters in establishing the degree of the health hazard.

Question: What percent of your budget is directed to preventive research?

Answer: Approximately 87 percent of the NIEHS budget is dedicated to preventive activities.

Question: How are the results of this research being translated into useful public information?

Answer: The Institute is actively engaged in a program of public information that widely disseminates the results of its research activities to both the lay public and the scientific community. The vehicles carrying this information include Technical Reports published by the National Toxicology Program which contain the results of NTP testing; the major television networks; local television and radio; national, syndicated, and local print media; and the Institute's own scientific journal,

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Environmental Health Perspectives, which is available internationally.

FACILITY

Question: You have been in your new facility for over two years. Has it met your needs to date, and will it accommodate your future plans?

Answer: The new NIEHS facility is now fully occupied and is functioning well. Scientists are pleased with the design. Furthermore, the new building permits the Institute to study potentially toxic chemicals in an environment that is safe for employees and reduces to a minimum the possibility of cross contamination betwen experiments.

At the time of design of the new facility, funds for construction were limited and certain specialized laboratories present in the old leased facility were not constructed so that the Institute continues to occupy leased facilities. In the future, consideration must be given to the replacement of the leased laboratories with an addition to the new facility.

PRIVATE SECTOR SUPPORT

Question: We know that joint Federal and private sector research efforts are attempting to share cost and benefit of environmental health studies. Has NIEHS participated in these efforts? If yes, have they been productive? If no, why not?

Answer: NIEHS does participate informally in joint efforts to share cost and benefits of environmental health studies with the private sector. A current example of such interaction is a joint meeting to be held this month (April 1985) between scientists with the Chemical Manufacturers Association Rubber additives program and scientists of the NIEHS/NTP staff to discuss activities by both groups. The purpose of the meeting is to insure that the programs in government and industry are complementary and not redundant. Such meetings are the result of continuing communication and information sharing between the two sectors. The cooperative activities between government and industry scientists have been productive in preventing duplication of efforts and in insuring that necessary studies are performed when needed.

PERSONNEL

Question: Has NIEHS had any difficulty in attracting or retaining competent, respected scientists, engineers, other professionals or staff? If so, what are the causes of the difficulty, and how can they be corrected? What ongoing programs, if any, does the institute have to recruit and retain high quality personnel?

Answer: We have experienced some difficulty in attracting senior staff members, particularly in certain areas such as pathology, where our salary structure is not competitive with private industry or academia. Relocation costs, particularly mortgage rates can also be a factor. I'm afraid most of these are beyond our control. We are making use of advertisements in scientific journals and involving

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our advisors and colleagues in attempting to recruit quality individuals and are being relatively successful. Our strongest attraction is the quality of our scientific progress and the opportunity to associate with other parts of NIH.

FTE

Question: You are requesting a reduction of FTEs in the intramural research program support even though the FY 1985 appropriation increased your intramural research request by almost $7 million. Am I correct in assuming that the $7 million will increase the number of research projects you will support?

Answer: The $7 million you refer to is an increase over the 1984 actual obligations level. The 1984 figure had been adjusted downward by $3 million due to an approved reprogramming request because of our inability to complete some facility engineering projects. These projects will be accomplished in 1985. Also, another $2.5 million is for mandatory increases and purchase of ADP equipment. Approximately $1.5 million is for expansion of specific research projects.

Question: Then how can you run more projects with less personnel?

Answer: As stated above, it is not a case of appreciably increasing the number of projects, but increasing the scope of existing projects. This expansion is not considered labor intensive.

INTRAMURAL

Question: The FY 1985 appropriation for intramural research was $54,566,000. Your current FY 1985 estimate is $359,000 less. Why have you reduced the FY 1985 budget by $359,000?

Answer: The reduction of $359,000 is related to two specific items. The Deficit Reduction Act, Section 2901, would require a reduction of $226,000 in such areas as travel, motor vehicles, publications, etc., and the Treasury-Postal Service Appropriation Act, 1985, Section 515, would require a reduction of $133,000 in consultant services.

Question: What is the effect of this reduction on your intramural research program?

Answer: We will try to assure that this administrative reduction will have minimal impact on the research programs.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: Administrative costs associated with grants could be decreased by increasing the number of tasks accomplished by means of electronic transfer of information rather than by manual means, by utilizing new technology for optical scan reading of application information with subsequent transfer to a computerized data base and

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high speed printer output, and by capturing grant file information on microfiche to reduce the volume of hard copy documents reproduced and the space required to maintain grant records and extra material grant files.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: The Productivity Council has been established to improve administrative efficiency. This group is made up of senior scientific and administrative staff and is charged with reviewing Institute policies, procedures and practices to ensure we are getting maximum efficiency, particularly in the research support areas. Operating procedures within the Extramural Program are subject to continuous review and discussion by staff in an effort to promote a more cost effective and efficient operation.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: Two procedural changes have recently been initiated to increase efficiency and lower administrative costs. These are 1) microfiche of grant files, 2) increased use of computers and word processors for informational purposes and office efficiency.

The use of microfiche permits a decrease in the number of printed copies of applications, summary statements, etc. needed for back-up material. The availability of microfiche in each office will permit each staff person to immediately respond to incoming calls, using the microfiche as the information base. Previously staff had to delay responses until the official file was available.

The ongoing computerization of the Extramural Program has permitted a more rapid access to grant information from the Division of Research Grants (DRG). This computerized information covers all phases of DRG's activity from receipt and assignment of applications to electronic transfer of the summary statement. The immediate availability of this information permits program staff to more efficiently utilize their time and to plan an orderly distribution of workload.

In addition, more administrative tasks are being accomplished by electronic transfer of information, saving time and personnel effort. These tasks include entry of grant award information into the central NIH data base system, preparation of hard copies of grant awards by means of a computerized system, and preparation of some review material that previously was accomplished manually.

Two contract changes that we have instituted recently to decrease administrative costs are the development of standardized automated RFP and contract workforms and the automation of our procurement planning system. Both of these changes should reduce the time and cost associated with the former manual methods that they replaced.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

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Answer: Appropriate and adequate review of all new and competing applications is an absolute requirement, therefore, NIEHS will continue to conduct peer review of all incoming applications assigned to the Institute for review. Efforts to decrease administrative costs have had no negative effect on the equitable and complete review of the research proposals.

REDUCING UNCERTAINTY

Question: What research has NIEHS performed to try to reduce the uncertainties rising from interspecies variability (including efforts to develop sound alternatives to animal testing), dose-response characteristics, and risk assessment methodologies and how has the Institute coordinated this research with other Federal agencies, the private sector, the international community, and academe?

Answer: A number of NIEHS research activities are directed at issues that are crucial to the reduction of uncertainty faced when dealing with low-dose, chronic, human exposures to toxic substances. First, in an effort to develop scientifically sound alternatives to animal testing, the Institute has conducted a significant research program on short-term in vitro tests for genetic toxicity. At present the NIEHS has probably the world's largest database of short-term test results. This and the equally unique NIEHS database for long-term rodent carcinogenicity studies are being used in a recently initiated project to examine systematically the predictivity of the former for the latter. This exercise will determine whether a battery of short-term in vitro tests can be constructed that will correlate well with the outcomes observed in the chronic rodent carcinogenicity studies. Depending upon the degree of predictivity found, short-term genetic toxicity tests may be useful to assist prioritizing chemicals for chronic carcinogenicity testing, or in certain cases may even act as a scientifically credible surrogate for the chronic carcinogenicity test. Additionally, the Institute, through financial support and leadership provided by members of its scientific staff, has played a major role in the collaborative study of short-term tests conducted by the International Program on Chemical Safety, World Health Organization.

Second, recognizing that interspecies variability is of fundamental importance to risk assessment, and that research on this key issue has been hampered by a dearth of available data, the NIEHS, in collaboration with the Department of Energy, is supporting a contract with Dr. Bruce Ames and the Lawrence Berkeley Laboratory/ University of California to study interspecies variability. The project has developed a large laboratory animal database to permit evaluation of the impact that various factors, both experimental ones and those that are species descriptors, have on the interspecies variability observed in chronic carcinogenicity studies.

Lastly, additional research aimed at the reduction of uncertainty in the human risk assessment process involves study of: (i) the impact of duration of exposure and length of subject follow-up on the estimation of working lifetime cancer risk, (ii) the particular initiator or promoter properties of toxic substances, (iii) monitoring of the effective dose delivered to a target sight, and (iv) pharmacokinetic considerations that can impact substantially on dose-response modeling and determinations of acceptable risk.

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TOXIC WASTE SITES

Question: Please describe the efforts by NIEHS to study ways to rank waste sites by their degree of hazard, i.e., to determine which sites should be cleaned up first. Also, please describe NIEHS's efforts to develop less costly, quicker, and more effective methods for cleaning up toxic materials and what procedures exist to inform other Federal agencies, e.g., the Environmental Protection Agency, of NIEHS research and is NIEHS coordinating its research with that performed in the private sector, other Federal entities, the international community, and academe?

Answer: The NIEHS is responding to the EPA's need to rank waste sites by their degree of hazard by providing information on the toxicities of chemicals found in such sites. This is done both by providing data on those chemicals that the NTP has tested in the past or is currently testing -- a large proportion of those chemicals commonly found in waste sites -- and by providing a mechanism for further testing to eliminate data gaps for those waste site chemicals not sufficiently tested.

Chemicals are selected for research and testing in the NIEHS/NTP based on nomination from Federal agencies and the general public, and final selections are approved by the NTP Executive Committee, a group composed of representatives of the key Federal agencies, including the EPA, involved in toxicology and public health protection. Research and testing plans are also announced in the Federal Register or in documents such as the NTP Annual Plan made available to the Federal agencies.

All NTP-generated study reports are publicly available, and those for chronic toxicity and carcinogenesis studies are provided to the key Federal agencies (including EPA) in the form of draft reports at the same time that they are sent to an external peer review board. In addition, should preliminary testing results indicate an overwhelmingly hazardous chemical effect potentially dangerous to the public, the key Federal agencies are notified of the preliminary findings through the NTP Executive Committee.

The NIEHS coordinates its research with other Federal entities and scientists in the international, academic and private sectors by maintaining a high visibility in toxicology, personal contacts with other leading scientific and regulatory organizations, and participation in and sponsorship of scientific meetings and symposia. In addition, its activities are communicated to the public yearly in the form of annual reports and plans.

GENETIC SCREENING

Question: Physical or chemical agents in a person's environment, be it occupational or non-occupational, may alter that person's genetic structure. Also, certain existing genetic factors may predispose an individual to environmental or occupational disease. Genetic screening may make it possible to prevent disease or detect its presence while it is still in an early and treatable stage. Has the Institute studied the limitations and promise of currently known techniques for determining the frequency of genetic mutation in humans?

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Answer: Over the past 25-35 years a number of methods for determining germ cell mutation frequencies in humans have been developed and attempted. These include the monitoring of sentinal phenotypes, sex-linked recessive mutations, fetal deaths, sex ratios and others. For a variety of reasons, none of these have proven particularly satisfactory usually because of the very low frequency of events being monitored and, therefore, the need to monitor such large populations. However, we are aware that developing electrophoretic and recombinant DNA technologies offer new methods to assess mutations in humans. We remain in communication with those working in human genetics in order to facilitate the transfer of new methods from the laboratory to human studies.

Question: Have you notified other Federal entities, academe, the private sector, and the international community of this research?

Answer: Research at NIEHS is published in peer-reviewed scientific journals and presented at scientific meetings in this country and abroad. In addition, researchers at NIEHS carry out collaborations formally and informally with many scientists outside the Institute.

Questions Submitted by Senator William Proxmire

ASBESTOS

Question: Dr. Rall, in your prepared opening statement you indicated that naturally occurring asbestos causes benign intestinal polyps in rats if given orally at the one percent level. Can you tell us what relevance this research has to human beings?

Answer: My opinion of the relevance of this finding to human health is as follows:

- A relatively high level (1% in the diet for lifetime) of a specific type (chrysotile) of asbestos produced benign tumors of the intestine only in male rats.
- A shorter fiber length of the same type of asbestos did not produce this effect.
- Other types of asbestos (amosite and crocidolite) did not cause a similar effect even though they, as well as chrysotile, are well known carcinogens if inhaled by animals as well as humans.

Therefore, this research suggests that the health hazards of asbestos exposure are primarily from inhalation. However, the response in male rats may support the need for an in-depth epidemiological study of people exposed to asbestos via ingestion.

1,3-BUTADIENE

Question: Dr. Rall, in your prepared statement you mentioned your study of the chemical butadiene, which is used to make artificial rubber. Is it true, as reported in the press, that you had to terminate the testing prematurely because so many mice were dying of cancer?

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Answer: Exposure of mice to air containing 0, 625 or 1,250 ppm butadiene produced marked increases in tumor rates at multiple organ sites in male and female mice at both exposure levels. The dose levels in the butadiene study were both below and slightly above the OSHA standard of 1000 ppm for this chemical. Furthermore, recent pharmacokinetic studies in mice indicate that over the exposure range of 8 to 800 ppm butadiene, pulmonary absorption and elimination in the urine or as CO?2? are linearly related to the inhaled concentration of butadiene. These findings raise the likelihood that butadiene may also elicit a carcinogenic response in mice concentrations lower than those used in the NTP study. Exposure levels to butadiene at most synthetic rubber facilities are well below the current OSHA standard of 1000 ppm. We do not know the details of exposure levels and excursions and without that information can not comment on an Emergency Temporary Standard.

APPLICATION OF TEST RESULTS

Question: Dr. Rall, your Institute is doing a great deal of excellent and sophisticated work. However, I wonder if your improved ability to detect environmental hazards is being fully used by the various regulatory agencies to improve the quality of life. Of course, that is the bottom line. Can you outline briefly any Federal or private actions that have been taken over the last year or so to implement the results of your studies?

Answer: The regulatory agencies participating in the NTP have utilized toxicology test data generated by the NTP on various environmental chemicals in their analyses of the need for regulation of these chemicals. As an example, the positive results from the NTP carcinogeneris study of 1,3-butadiene in mice were utilized by EPA in deciding to initiate a 180-day review of the chemical under Section 4(f) of the Toxic Substances Control Act. Similarly, OSHA has published a notice in the Federal Register requesting interested parties to submit data and comments relevant to determining the risk of potential adverse health effects of 1,3-butadiene. In addition, a number of recent proposed regulatory actions have been based in part on data from NTP toxicology studies. As an example, EPA made use of the positive results from the two NTP/NCI carcinogenesis bioassays of ethylene dibromide in its decision to eliminate certain uses of this chemical as a pesticide.

The regulatory agencies have also requested that the NTP undertake additional toxicology testing of chemicals demonstrated to have adverse effects in completed NTP studies in order to better elucidate their mechanisms of action.

For example, the agencies have requested further studies of 1,3-butadiene to develop dose response carcinogenicity data in mice and to investigate the species differences in sensitivity to the carcinogenic affects of the chemical in rodents. In addition, the agencies supported genotoxicity and reproductive effects testing of the chemical. Based on preliminary results made available to agency representatives from the ongoing NTP carcinogenicity study of methyl carbamate, these persons requested genotoxicity, reproductive effects and pharmacokinetic testing of the chemical.

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TELONE

Question: Dr. Rall, you indicated in your opening testimony that a widely used soil fumigant, telone, caused cancer of the bladder, stomach, lungs and liver in test animals. Can you tell us what steps have been taken to control the use of this fumigant as a result of those findings?

Answer: There has been development in three areas. It is the understanding that, the manufacturer, Dow Chemical Co., voluntarily removed Telone II from the markets in Long Island and Florida fearing the contamination of ground water in these areas. Dow Chemical Co. is also in the process of petition to EPA to change the Telone II registration status from "General use pesticide" to "restricted use pesticide" and to change the Telone II label such that its carcinogenic properties will be incorporated as a warning. EPA is studying this petition.

Effective July 1, 1985, the State of California will not allow the registration, use and selling of any economic poisons containing greater than 0.5% 1,2-dichloropropane, a minor ingredient of Telone II. There is no regulation yet on 1,3-dichloropropene, the major ingredient of Telone II because of lack of evidence of ground water contamination.

Based on the peer reviewed draft report from the NTP on Telone II, EPA is evaluating the status of Telone II. No decision has been made yet.

CENTER AWARDS

Question: Dr. Rall, material submitted to the Committee explaining the effect of Congressional appropriation action on your 1985 budget indicates that you intended to make 14 center awards in 1984 but actually made only 12. Was that because the quality of the proposals were below your expectations?

Answer: Essentially, that is correct. We had anticipated funding two new Marine and Freshwater Biomedical Centers in FY 1984 but the applications reviewed at that time did not receive a high enough priority score to be funded.

Questions Submitted by Senator Lawton Chiles

Question: We're beginning to hear a lot more about biotechnology. Some have called it the last great scientific revolution of the 20th century while others have called it the next great scientific threat to man and his environment. Certainly the potential is significant. However, legitimate concerns have been raised regarding release of genetically engineered substances and organisms into the environment. The National Institutes of Health Recombinant DNA Advisory Committee (RAC) has been the leader in providing advice on biotechnology and has evolved guidelines that have allowed biotechnology research to go forward. Now, biotechnology is beginning to move out of the laboratory and into the marketplace. How do you see the RAC's function changing?

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Answer: Since 1974, when it was first established, the RAC has continued to evolve. For example, in the early years RAC concentration consideration of small scale recombinant DNA experiments in bacteria, conducted in the laboratory. Later it developed safety standards for large scale applications. Subsequently it considered proposed field tests, taking genetically engineered organisms out of the laboratory. Most recently the RAC has begun to consider human gene therapy. It is expected that, as new scientific opportunities emerge in the future, the RAC will continue to evolve in order to deal with them.

Question: How does the RAC interact with other agencies of the Federal Government charged with the regulation or oversight of biotechnology?

Answer: Federal agencies with representatives on the RAC are the following: National Science Foundation; Department of Agriculture; Environmental Protection Agency; Food and Drug Administration; Department of State; Veterans Administration; Department of Energy; Centers for Disease Control; National Institute for Occupational Safety and Health; Department of Commerce; Department of Interior; Department of Transportation; National Aeronautics and Space Administration; Department of Labor; Department of Defense; and Office of Science and Technology Policy. These agencies participate actively in meetings of the full RAC and of RAC subcommittees and working groups.

Question: As you know, the Cabinet Council Working Group on Biotechnology recently issued its proposal for a framework for regulation of biotechnology. What was NIH's role in this effort and what is your opinion of the proposal?

Answer: The NIH has been an active participant in the deliberations of the Cabinet Council Working Group on Biotechnology. I believe that the proposal issued for public comment in the December 31, 1984, Federal Register represents a promising and valid approach. The proposal would retain the RAC at NIH, but establish RAC-like scientific advisory committees at four additional agencies: the Environmental Protection Agency; the Food and Drug Administration; the Department of Agriculture; and the National Science Foundation.

Question: Are some types of genetically engineered products or substances inherently riskier than others?

Answer: Some products or substances would indeed be riskier than others; consequently, the RAC considers each proposal it reviews on a case-by-case basis.

Question: What are the relatively generic problems associated with the release of novel organisms?

Answer: Among some generic issues to be considered in the assessment of risk of release of novel organisms are the following: Are the genetically engineered organisms truly novel or do similar organisms already exist in nature? Will the organisms survive after release? Will they become established in the environment? Are they making a harmful product? What is the probability of the product reaching a site where it might do harm? What is the probability of the organism transferring its novel DNA to another organism?

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Question: Do you think we will ever have a totally complete predictive model for assessing the environmental effects of biotechnology releases?

Answer: We will probably never have a totally complete and totally accurate predictive model for such assessment. However, in certain cases, as in the field test proposed by the University of California with ice-nucleation-minus bacteria, I believe we have enough information today to predict that there will be no significant impact on the environment.

Question: Once release has occurred, how is monitoring done? Will different releases require different monitoring systems?

Answer: No environmental release of organisms containing recombinant DNA has actually occurred. In the future, when NIH approves such releases we will stipulate monitoring procedures. Different releases will involve different monitoring systems.

Question: Is any research regarding post-release monitoring being done?

Answer: Research is being done on the properities of non-genetically-engineered organisms both in the laboratory and in the environment, as well as on the properties of genetically engineered organisms in the laboratory. Results from this research will enable us to better design monitoring systems when genetically engineered organisms are released.

Question: Are any other agencies engaged in risk assessment research on genetically engineered products or substances to your knowledge? If so, which ones?

Answer: In addition to the NIH, research on genetically engineered products or substances that may have applicability in risk assessment is being performed by the National Science Foundation, the Food and Drug Administration, the Environmental Protection Agency, and the Department of Agriculture.

Question: Are these research efforts coordinated in any way with work being done at NIH?

Answer: Research efforts in this area are coordinated through the NIH Recombinant DNA Advisory Committee and the Cabinet Council Working Group on Biotechnology.

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NATIONAL INSTITUTE ON AGING

STATEMENT OF DR. T. FRANKLIN WILLIAMS, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTE OF HEALTH

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DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. The next Institute is of special concern to me, and we will hear from Dr. T. Franklin Williams, Director of the National Institute on the Aging. If Dr. Williams would be seated. We welcome you before the committee.

Before you proceed, we will insert your prepared statement in the record.

[The statement follows:]

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Statement of Dr. T. Franklin Williams

I am pleased to appear before you today to report on recent advances and new opportunities in our quest for knowledge of the aging process and the means of delaying onset of disease and disability. The increasing longevity that we have experienced is testimony to our society's ability to create conditions for longer life. The vast majority of our elderly population enjoy good health and independence, living well into old age. However, there is a segment of this population which is less fortunate. Each year approximately 1.3 million people, of which one million are elderly, will spend time in nursing homes. For each older person in a nursing home, there is one at home with equal disability. While the elderly represent only 12 percent of our population, they account for 29 percent of all health care costs.

Over the past ten years, knowledge of the disease-states common to the elderly and about the changes which occur with aging has improved significantly. However, important scientific questions remain unanswered. Continued research is essential to understand the mechanisms of aging and to understand the nature of age-associated diseases and disorders -- such as Alzheimer disease, osteoarthritis, and urinary incontinence. This research is vital to assure rational and cost effective plans for providing health care to our present and future elderly.

Research on Alzheimer disease, the most common form of dementia among the aged, continues to be a high priority for the NIA, as Institute scientists and grantees attempt to identify what causes the disease and how it can be treated or prevented. Researchers studying basic cell metabolism at the Harvard Medical School and the McLean Hospital in Belmont, Massachusetts, may have uncovered one clue to the mechanisms underlying this illness.

In a series of investigations supported by the NIA, Drs. Charles Marotta and Elizabeth Sajdel-Sulkowska have found a biochemical abnormality that impedes production of new proteins in Alzheimer brain tissue. In the diseased brains, the investigators found little more than half the normal amounts of ribonucleic acid (RNA). RNA is a key chemical in the production of protein, a process that is critical to the life of the cell. A closer look linked the lower levels of RNA to the presence of increased ribonuclease activity. In the healthy brain, ribonuclease breaks down RNA, but its activity is closely controlled by an inhibitor protein. In the Alzheimer brain, ribonuclease activity was found to be higher, due to a deficiency in the inhibitor, resulting in more destruction of vitally important RNA resulting in protein synthesis of cellular proteins such as enzymes.

It is not possible to state if this change marks the onset of Alzheimer disease, or if it is just one of a series of events that takes place as brain cells begin to die. At the very least, Marotta and Sajdel-Sulkowska have identified a metabolic defect in Alzheimer disease which might have implications for improved diagnosis of Alzheimer disease in living patients. If, as the investigators speculate, decreased protein synthesis results in the chemical changes and brain cell death characteristic of Alzheimer disease, then we are possibly one step closer to finding out what causes this debilitating illness.

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In our intramural Laboratory of Neurosciences based in the Clinical Center in Bethesda, the course of Alzheimer disease and other dementias is being examined in patient volunteers with a variety of clinical test instruments including positron emission tomography (PET). The Laboratory of Neurosciences has already shown with PET that regional reductions in brain activity occur in early Alzheimer disease. PET may be useful for the differential diagnosis of the dementias and for monitoring the course of the disease in clinical trials of different therapies.

An aggressive attack by the NIA on this devastating disease associated with old age has given hope that treatments may one day be available for those who suffer from this form of mental impairment. The establishment during 1984 of five centers for Alzheimer research provides a major step towards intensifying research in this important disease. The centers share a common goal of enhancing research on Alzheimer disease (AD) by providing the resources and environment for collaborative, multidisciplinary studies. Research projects will attempt to identify the causes of this disease and search for new drug treatments which may compensate for loss of chemical activity. The centers will also broadly disseminate knowledge about AD to scientists and the lay public.

A workshop on molecular genetics, held in September 1984, urged increased attention to using molecular genetic techniques to study aging. This should provide insight into the mechanisms of aging and may permit a better understanding of age-related diseases. In the last few years, powerful new techniques have emerged in molecular biology. The procedures of molecular cloning and gene transfer have provided valuable information on the nature of carcinogenesis at the molecular level. It is now timely to apply this technology to the examination of the nature of aging at the molecular level.

In order to provide leadership in this field in our intramural program and to aid our established laboratories in extending their research capabilities through the use of these new techniques, NIA is establishing an intramural laboratory of molecular genetics. Research will be directed at examining changes that occur with aging in gene function and structure. Using molecular genetic techniques, it may be possible to localize the gene(s) responsible for the inherited form of Alzheimer disease. It might then be possible to isolate, transcribe, and translate these sequences, which in turn could lead to the elucidation of molecular lesions involved in this devastating illness.

NIA's Baltimore Longitudinal Study of Aging (BLSA) has done much to improve our understanding of the aging process. This study, conducted by the NIA's Gerontology Research Center, is in its twenty-sixth year for males and sixth year for females and currently includes about 900 active participants. Participants in this study come to the GRC every 2 years for a series of medical, genetic, biochemical, physiological, and behavioral tests. Each additional cycle of examinations enriches our knowledge base concerning normative aging. Among the significant results from this study during the past year is the finding that in persons who are free of any evidence of heart disease there is no significant decline in maximum heart capacity with age. While there is a slower heart rate response to exercise stress, the older heart compensates by having a larger effective volume maintaining the same heart output.

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Many of the changes observed with aging may be reversible. There is a pressing need to discover how, why, and under what conditions age-related declines may be prevented, reversed or ameliorated. Recent research findings are suggesting how the productive middle years might be extended, how many disabilities of old age might be prevented or postponed, and how the costs of health care and dependency might be contained. Contrary to prevalent misconceptions, few healthy individuals up to age 60, and less then half even at age 80, display significant decrements in intellectual test performance as they grow older. With training and incentives, elderly people can learn to perform as well on these tests as people 20 years younger.

A number of disorders and diseases that afflict older people and result in disability and institutionalization have received too little research attention from the medical community. These include the major types of functional disabilities such as incontinence, falls and hip fractures. Through NIA's Teaching Nursing Home Program (TNH), support for clinical research in geriatrics is increasing dramatically. The NIA TNH program has provided the example for private organizations to initiate programs involving a nursing home and medical school to examine basic clinical problems. While 7 TNH programs have been funded, 10 times that number of medical and nursing schools have begun collaborations with long-term care facilities.

Along with studying the processes of aging, it is the role of NIA to overcome negative myths and stereotypes of aging which so often interfere with normal healthy aging. Negative attitudes can be harmful when they keep people from receiving — or sometimes from seeking -- the medical care that they need. Urinary incontinence is a cardinal example. The cost of this disorder is estimated to be $2 billion annually. At the University of California at San Francisco, Linda Mitteness has found that urinary incontinence goes largely untreated because the elderly and the people in the community who help them obtain medical care are ignorant about the causes, consequences and possibilities for treatment and cure. The NIA, in collaboration with the Division of Nursing, HRSA, has initiated a modest cooperative project, in 5 research settings, to test the effectiveness of an investigative approach to controlling incontinence through behavioral and biofeedback treatments, an approach developed in the NIA's Laboratory of Behavioral Sciences in Baltimore.

Until recently the population aged 85 and over has been relatively invisible. NIA researchers were among the first to alert the scientific community to the fact that the 85+ population has been growing three times as fast as the rest of the population over age 65. By the year 2000 -- in the next 15 years -- the number of persons aged 85 and older will more than double, from 2.6 to 5.4 million. Federal projections in the past have consistently underestimated the growth of the 85+ population. Despite the fact that they are substantial users of health care and other services (i.e., by one estimate, the Federal government spends about $50 billion annually in services and transfer payments), less is known about this age group than about any other. To encourage research in this area, NIA recently issued a program announcement.

Many studies document, but few attempt to explain, the paradox that women report more illness and health care utilization than men, yet today life expectancy is consistently higher at every age for women than for men. This difference in life expectancy is not

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invariant, but has been increasing rapidly throughout the century. These changes create a special opportunity for research on the sources of the gender differences in health and longevity.

By the year 2000 the number of Americans aged 65 and over is expected to reach 36 million -- 10 million more than in 1980. This projection makes it imperative that we prepare now for greater demands for health services. The Institute has joined several other Government agencies in making comprehensive plans to improve and expand education and training in all aspects of geriatrics and gerontology. The goals are to increase the number of professionals and allied personnel involved in caring for the elderly at community clinics and agencies, hospitals, and long-term care facilities, and to improve their knowledge about preventing and treating diseases that affect older people. The training initiative is the result of efforts by a Department of Health and Human Services (DHHS) task force. A report outlining a plan of action was submitted to Congress in February 1984.

In response to the report's recommendations, each participating agency is expanding its training efforts in gerontology and geriatrics. The NIA has added two new grant mechanisms. The new Geriatric Leadership Academic Award will support faculty leaders at health professional and educational institutions which develop or improve research and teaching programs in aging. The Complementary and Supplementary Training Awards for Research on Aging will help a variety of well-established research training programs to add investigators whom they will train for careers in aging.

Mr. Chairman, the 1986 budget request for this Institute is $134,758,000, a decrease of $9,831,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particulary with respect to the number of competing research project grants and centers funded. Specifically, in 1985 this Institute will fund 154 new and competing grants of which 16 will receive 3 years of support. In addition, we will fund 3 centers, of which 3 will receive 2 years of support.

I will be happy to answer any questions.

Biography of Dr. T. Franklin Williams

Birthdate: November 26, 1921 - Belmont, North Carolina

Education: B.S., University of North Carolina, 1942; M.A., Columbia University, 1943; M.D., (Cum Laude) Harvard Medical School, 1950

Professional History: 1983 to present, Director, National Institute on Aging, NIH; 1983, J. Lowell Orbison Alumni Distinguished Service Professor; 1982-1983, Director of the Geriatric Unit, Monroe Community Hospital, Rochester, N.Y.; 1980-1983, Co-Director, Center on Aging, University of Rochester Medical Center; 1968-present, Professor of Medicine and of Preventive, Family and Rehabilitation Medicine, University of Rochester; 1968-1982, Professor of Radiation Biology and Biophysics, University of Rochester; 1968-1982, Medical Director,

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Monroe Community Hospital, Rochester, N.Y.; 1977, L.S. McLeod Visiting Professor of Geriatric Medicine, University of Adelaide and South Australia Postgraduate Medical Education Association; 1956-1968, Instructor to Professor of Medicine and of Preventive Medicine, University of North Carolina; 1954-1956, Fellow in Medicine, University of North Carolina; 1953-1954, Assistant in Medicine, Boston University; 1953-1954, Senior Resident Physician, Boston Veterans Administration Hospital; 1950-1953, Intern and Assistant Resident Physician, John Hopkins Hospital; 1942-1943, Assistant in Chemistry, Columbia University.

Military Service: 1983 to present, Assistant Surgeon General, U.S. Public Health Service; 1943-1946, Communications Officer, U.S. Naval Reserve, active duty.

Societies and Associations: American Association for the Advancement of Science (Fellow); American College of Physicians (Fellow); American Federation for Clinical Research; American Public Health Association (Fellow); American Society of Human Genetics; American Geriatrics Society; American Diabetes Association; Society for Experimental Biology and Medicine Rochester Academy of Medicine; New York and Monroe County Medical Societies; Gerontological Society of America; New York State Public Health Association; Institute of Medicine, National Academy of Sciences; The Royal Society of Medicine; and Academia Medicorum Litteratorum.

Honors and Awards: Phi Beta Kappa; Alpha Omega Alpha; Sigma Xi; Member, Institute of Medicine; Diplomate, American Board of Internal Medicine; Diplomate, National Board of Medical Examiners; Markle Scholar in the Medical Sciences; Special Fellow, Department of Physiology, Vanderbilt University; and Honorary Member, American Academy of Orthopedic Surgeons.

Publications: Author of over 112 scientific papers and abstracts.

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OPENING REMARKS

Dr. WILLIAMS. Thank you.

Senator WEICKER. You said earlier that people aged 65 and older account for almost 30 percent of all health care costs, and by the year 2000 the number of people aged 85 and older will almost double. I am looking forward to your statement, so why don't you proceed with that. I again have to say at the outset that with these statistics, I initiated a small $5 million program in last year's budget to get the medical schools, the various universities of the Nation onto this subject. Out of 122 medical schools, there were only 2 that had programs to teach their students geriatrics in the sense of future practice. I don't know how you are going to handle these numbers unless you have men and women trained to deal with it coming out of medical school. These statistics, and the administration's answer this year is to throw out the program. I will put it back in. I am just anxious to listen to your testimony and respond to our questions because I just don't see how anybody can deny what is occuring in this Nation. It seems to me as a layman, I do not have the expertise that you have, we are ill prepared for something that is coming over that hill just as sure as the sun is going to rise tomorrow.

Please proceed.

INTRODUCTION OF ASSOCIATES

Dr. WILLIAMS. Thank you, Senator Weicker and Senator Chiles.

Let me introduce Ms. Karyn Ross, our Budget Officer, and Dr. Edward Schneider, our Deputy Director. You have received my prepared opening statement. At this time, I would like to highlight a few of the recent accomplishments in our high priority research areas.

NIA RESEARCH ACCOMPLISHMENTS

Our highest priority continues to be Alzheimer disease in the elderly. This disease is estimated to cost $28 to $35 billion per year in this Nation. One of the most pressing needs in this field is the ability to make an accurate diagnosis early in the course of the disease when efforts at treatment may have better chances of success. In our Institute's laboratory of neurosciences, the use of the positron emission tomography scan to measure metabolism in different regions of the brain has been correlated with changes in mental function tests, with the demonstration of early differences between normal aging persons and those with Alzheimer disease. This work raises the possibility of early detection of patients with this condition.

Other related research supported by the NIA is proceeding to isolate the abnormal protein of the brain lesions of this disease by developing a specific monoclonal antibody to this protein. Such an antibody may help detect Alzheimer disease in early stages through tests of serum or spinal fluid.

At one of the five Alzheimer disease research centers funded last

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year, the use of nuclear magnetic resonnance has helped distinguish multiinfarct dementia from Alzheimer disease. It is difficult to make this distinction with the CAT scan alone, for example.

Other exciting research is advancing on possible causes of Alzheimer disease, including the possibility that a virus or virus-like particle may be a causative agent. One of the highlights of the past year was the finding that another form of dementia had infectious particles associated with it which are apparently similar to the dementing disease of scrapie in sheep. Also, in relation to possible genetic causes of Alzheimer disease, investigators at another of the Alzheimer disease research centers have confirmed that there is a strong genetic component in certain instances of this disease. This finding lays the groundwork for applying techniques of molecular genetics, about which much has been said in these hearings, to attempting to identify the specific genetic abnormality.

Another high priority area is that of osteoarthritis, which is the most common cause of limitation of function in people. As was noted yesterday, it has been relatively neglected in research efforts up to now. Our Institute, along with the National Institute of Arthritis, Diabetes, Digestive, and Kidney Diseases, will shortly be holding a major research workshop on osteoarthritis. Work already accomplished has shown clear differences in the characteristics of the cartilage in persons who develop osteoarthritis compared to the cartilage of people who do not. This is another research area where techniques of molecular genetics can be applied.

In this area, that is osteoarthritis, as well as a number of others, there is close collaboration between the NIA and other NIH institutes and Federal agencies. Another example is our collaboration with the Division of Nursing of the Health Resources and Services Administration on a clinical trial on urinary incontinence in the elderly. We have also collaborated with health researchers at the Bureau of Health Professions in their work on geriatric education.

I have given a few examples just to illustrate the quickening pace of both basic and clinical research in the field of aging. Other high priority areas are referred to in our written remarks.

I would like to close, Senator Weicker, by emphasizing again this year as last the high importance we attach to training academic leaders for research and teaching in aging and geriatrics. This training is important both to continue to advance research and to reach medical and other professional students, all of whom need to need to know more about aging. I will be very happy to respond to questions.

ALZHEIMER DISEASE

Senator WEICKER. You mentioned the matter of Alzheimer disease being a high priority. As I understand it, the total NIH funding for Alzheimer is $46 million?

Dr. WILLIAMS. Yes, sir.

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Senator WEICKER. That was the 1985 funding. A portion of the 1985 funding was $30 million——

Dr. WILLIAMS. The NIA total estimate for fiscal year 1985 is $29.8 million.

Senator WEICKER. The 1986 request is $25 million, am I right on that?

Dr. WILLIAMS. Our figures show a fiscal year 1986 estimate of about $25 million for our Alzheimer program, excluding multiyear funds from fiscal year 1985.

In 1985, the appropriation level estimate is about $30 million.

Senator WEICKER. For 1986, it is $25 million?

Dr. WILLIAMS. Yes, sir.

Senator WEICKER. Well, I don't understand how those figures translate into either the highest priority or the increase insofar as those afflicted with the disease. I don't understand that at all. It doesn't seem to be either giving the highest priority nor even meeting the needs of the increased population that is affected here.

Dr. WYNGAARDEN. May I comment on the difference between dollar estimate and program estimate? The actual expenditure on Alzheimer's disease at NIH in 1984 was $35 million. The budget estimate for 1985 is $46 million, but some of that would be in forward funding, according to the present proposal. So the actual program level in 1985 would be $42 million. The actual program level in 1986 would be $43 million. So it does show a progression if you allocate the dollars to the year in which the work is actually performed.

Senator WEICKER. In effect it is a borrow from 1985?

Dr. WILLIAMS. Yes.

Senator WEICKER. I am not going to belabor it. I have already concentrated on it. I just get very, very tired of this administration telling me about its priorities of infant mortality, priority in Alzheimer's and yet the dollar requests just don't match the rhetoric. I think the American public ought to know that. It is absolutely—whether it is children, whether it's retarded, whether it's the aged, these budgets do not reflect a concern commensurate with the adjectives and adverbs.

NIH TASK FORCE ON NURSING

Dr. Williams, you chaired the NIH task force—this is a question from Senator Inouye—you chaired the NIH task force on nursing which we requested last year. Would you provide for the record a brief overview of your recommendations?

Dr. WILLIAMS. The written report of the NIH task force on nursing research is now available. I will be very glad to provide the executive summary of the report for the record. I will also submit a copy of the entire report under separate cover.

[The information follows:]

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EXECUTIVE SUMMARY

Introduction

This is the report from a six month study of nursing research at the National Institutes of Health (NIH). The Director, NIH established the NIH Task Force on Nursing Research to examine NIH's role in nursing research. Specifically, the charge to the Task Force was: to assess the NIH current support of nursing research; to evaluate the feasibility of increasing NIH support of nursing research consistent with the NIH mission; and to examine the current and potential role of nurses on NIH peer review groups, advisory committees, councils and boards. The work of the Task Force was to be carried out using only available data. The NIH Task Force was chaired by the Director, National Institute on Aging (NIA). The Task Force members included five senior NIH administrators. Four ex-officio members, three from other areas of the Public Health Service (PHS) and one from the Division of Legislative Analysis, Office of the Director, NIH also were appointed to the Task Force. Each of the NIH Bureaus, Institutes and Divisions desigated a representative to work with the Task Force. In addition, seven consultants on nursing research submitted statements on nursing research issues and met with the Task Force.

Definition and Scope of Study

The Task Force defined nursing research on two dimensions:

1. Research conducted by the nurse principal investigator: scientific inquiry in the causes, diagnosis and prevention of diseases, in the promotion of health, in the processes of human growth and development, and in the biological effects of environmental contaminants.

2. Nursing care research: research directed to understanding the nursing care of individuals and groups and the biological, physiological, social, behavioral and environmental mechanisms influencing health and disease which are relevant to nursing care. Nursing research develops knowledge about health and the promotion of health over the full lifespan, care of persons with health problems and disabilities, and nursing actions to enhance the ability of individuals to respond effectively to actual or potential health problems.

The definition of nursing research is a working definition to capture the nursing research activities at the NIH only. The Task Force chose to accommodate both the research responsibility of the NIH (dimension 1 of the definition) and one area of the entire domain of nursing research judged to be appropriate to the Task Force charge (dimension 2).

The scope of activities to be delineated in this study was further defined in accordance with the NIH mission to include clinical research training of nurses, and the development of nurse researchers. Research that involves nursing but the project is not headed by a nurse principal investigator was also identified for inclusion. Other activities (e.g., nurse members on councils, boards

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and review groups) also are included. Activities are identified within program area; extramural and intramural and as current or future. The data were accessed through manual searches by each of the BIDs and through the NIH IMPAC and CRISP data systems. The restriction to use only available data posed difficulty in data acquisition. The data systems do not identify the nurse principal investigator, nor specifically classify nursing research nor abstract subprojects of multiple project awards. In addition, funding of subprojects in multiple project awards can not always be dissociated. These factors may have resulted in an undercount of nursing research activities and funding levels.

Findings

The Task Force found that:

- Nursing research and training are established within a number of extramural and intramural programs of NIH.

- Sixty-four, FY 1984 applications were identified from schools, departments or colleges of nursing. The total request was $6.4 million. The total FY 1984 award was $1.5 million. Forty-one of the FY 1984 applications were competing; 16 of the competing applications were approved and 38% (six applications) of those eligible for funding were awarded. The average priority score for the awarded projects was 165.

- The 64 FY 1984 applications were assigned to 11 BIDs with 10 or more each being assigned to NCI, NICHD, DRR and NIA. Fifty-eight percent of these applications were ROIs, traditional research projects. The ROIs submitted by the schools, departments of colleges of nursing focus primarily in maternal and child health, aging and cancer.

- In FY 1983, 108 awards were made that involved nursing research activities. Twenty-eight of these were headed by nurse principal investigators. The awards represent $6,646,682 in funds; $1,411,325 of the total support was to nurse principal investigators.

- In FY 1983, 108 awards were made by eight BIDs with over half of the awards being made by NCI, NIA and DRR. The awards were made through 14 support mechanisms. However, nearly half of the awards were made through four types of support; i.e., Comprehensive Centers (P60), Biomedical Research Support Grants (S07), Specialized Centers (P50), and Research Program Projects (P01).

These type of awards offer an opportunity for research by nurses in an interdisciplinary setting which is valued by the nursing research community as evidenced in the literature on nursing research priorities and in the statements of the nurse consultants to the Task Force.

- Only two awards specific to the development of the nurse researchers (NINCDS, FY-1983 and NCI, FY-1984) were

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found. A concern brought to the attention of the Task Force by the nurse consultants and documented in the literature is that the nursing profession requires more doctorally prepared nurses to conduct nursing research.

- In the intramural program nurse researchers are participating in or conducting research through the BID/Department of Nursing, Nursing Research Committee at the Clinical Center. Twenty projects were identified.

- A number of other types of activities in nursing research are being supported (e.g., conferences, research seminars, workshops, etc.).

- No comprehensive research and training activities in nursing research, integrated with individual BID program plans, were found; however, this work is now being initiated in some of the BIDs (e.g., nursing oncology research priority issues, NCI).

- There is a nurse member on each of the twelve BID intramural IRBs. There are nurse members on only eight of the more than 160 scientific review committees, advisory councils and boards at NIH.

Conclusion

The Task Force concluded that:

- Nursing research activities currently being supported are consistent with the NIH mission.

- The nursing research environment could be enhanced at NIH through administrative activities: fostering the awareness of nursing research within NIH; identifying nursing research priorities compatible with the BIDs' missions and developing program efforts in these areas; encouraging more collaborative and interdisciplinary research and training within the extramural and intramural programs; assisting in the development of nurse researchers; assisting in the enhancement of the research skills of senior nurse researchers; providing technical assistance to institutions with a nursing research capacity; increasing the number of nurse advisors and reviewers within the existing structure; and assuring that the data on nursing research activities at NIH can be accessed.

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STATISTICS ON THE ELDERLY POPULATION

Senator WEICKER. Let me get my statistics clear, if I can, only because I need them for reference here. You say the 85 population will double by the year 2000?

Dr. WILLIAMS. That is right. The population age 85 and older will double between now and the year 2000. Right now, it is about 2.6 million and by the year 2000 it will be about 5.6 million.

Senator WEICKER. 2.6 million, and will be what?

Dr. WILLIAMS. 5.6 million by the year 2000.

Senator WEICKER. How about the same thing for age 65 and older?

Dr. WILLIAMS. That age group will grow from about 27 million now to about 36 million by the year 2000. Actually, the population age 65 and older will double by the year 2020. That is, we will have about 52 million people aged 65 and older by the year 2020. Given the longevity today, that is well within the lifetime of virtually everybody in this room. [Laughter.]

HEALTH CARE COSTS

Senator WEICKER. The over 65 population makes up 12 percent of our population. It accounts for 30 percent of our health costs; is that correct?

Dr. WILLIAMS. Yes, sir, approximately.

Senator WEICKER. About 30 percent of health costs. What are the most substantial parts of that?

Dr. WILLIAMS. That cost is spread over the whole spectrum of health costs. The elderly account for a large proportion of hospital care; they account for most nursing home and other long-term care; and they account for a sizable proportion of primary office visit doctor care.

Senator WEICKER. What does that 30 percent translate to in dollars? Do you have any idea?

Dr. WILLIAMS. The figure is something like $100 billion, but that may be low.

Senator WEICKER. $370 billion total health costs.

Dr. WILLIAMS. Then 30 percent would be nearer $110 billion.

PREVENTION RESEARCH

Senator WEICKER. So you are talking about roughly $110 billion.

I have further questions, Dr. Williams, for response to the record. One question here. In a speech before the American Pharmaceutical Association, Dr. Wyngaarden said 28 percent of the NIH funds are directed to preventive research. What kind of preventive research is being done by your Institute?

Dr. WILLIAMS. This is one of our six or seven highest priority areas which deal with promotion of health, maintenance of health, and maintenance of effective functioning in older people. Actually, our research touches on prevention in the elderly in a number of areas. Some of the most obvious is in the promotion of research on nutrition and exercise.

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These are areas that have been relatively neglected until very recently. Some of the most interesting work, in my view, is going on in the area of exercise, in carefully controlled studies of sustained exercise regimens in previously sedentary older people, where the results show that improvement in aerobic capacity can be achieved with about the same percent effectiveness in older people as younger.

In addition, our efforts on the functional disabilities which cause the greatest distress and which are the greatest causes for admission to nursing homes are really addressed at prevention. This involves, in addition to work on dementia already referred to, work on mobility problems, osteoarthritis, falls, osteoporosis, hip fractures, and urinary incontinence. All of these efforts are addressed to prevention of the loss of functioning in older people.

There are other types of examples that deal with efforts at behavorial improvement in performance in the life style aspects—nonsmoking and similar goals in older people.

Senator WEICKER. Senator Proxmire?

EXERCISE AND THE ELDERLY

Senator PROXMIRE. Thank you, Mr. Chairman.

I got in on the end of your aerobic observation. I can tell you, as you get older, your aerobic capacity does not improve. I used to be able to run the 5 miles to work in 35 minutes when I was 50. Now I am 69, almost 70, and it takes me 40 minutes. [Laughter.]

I can tell I am slowing down. I figure in a few years I will be dragging.

Dr. WILLIAMS. In a group of sedentary people age 69 to 90, researchers have found an average 40 percent improvement in aerobic capacity with a sustained exercise program. The levels reached on average were the same as in younger people.

Senator PROXMIRE. You didn't find a slowdown as you progressed toward 90? [Laughter.]

Dr. WILLIAMS. This is a cross-sectional study over about 1 year's time. I don't doubt there is some slowdown——

[Laughter.]

Dr. WILLIAMS [continuing]. But I think the slowdown may have been exaggerated.

Senator PROXMIRE. Well, this is encouraging. Yesterday we had encouragement too. We were told the libido of people 85 years old is something we had to be concerned about because certain drugs might reduce it, but that isn't something that bothers me very much. [Laughter.]

FOSTER GRANDPARENT PROGRAM

Dr. Williams, in May 1984 your Institute awarded a 5-year grant to the University of California at Irvine. The title of the grant was intervention effects on psychobiological decline in aging. The grant is for $3.1 million in direct costs and if we assume that indirect costs will be around 41 percent then the total cost of the project will be $4.4 million.

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As I understand the project, it will compare the mental and physical health of participants in the Foster Grandparent Program with two other groups. I will predict that the study will find that those who are physically and mentally active will fare better than those who are not and that the Foster Grandparent Program provides systematic physical and mental activity that is quite beneficial in slowing the aging process. But at a time when research funds are so tight, does it make sense to spend $4.5 million to find out what we already know?

Dr. WILLIAMS. In this area as so many, what we often think we know—I am speaking a little more generally now, sir, what we think we know doesn't always come out exactly the way we first think it may come out. This is particularly so in some of these intergenerational relationships. We have a society that is a four and five generation society now, really for the first time in world history. A lot of changes are occurring in these intergenerational relationships, with grandchildren becoming the primary support for grandparents rather than the middle generation. The middle generation in almost a majority of cases now may have divorce and separation in its history.

I would take the general position that we are justified in trying to examine these questions and learn more about what is effective and what isn't.

Senator PROXMIRE. The Foster Grandparent Program application received a priority score of 176. What is the cutoff score for grants at the Institute on Aging?

Dr. WILLIAMS. Last year our cutoff score was 190, approximately. This year in the first council working under the fiscal year 1985 appropriation guidelines, we were funding up to 190 also. At present, based on the President's budget, we are funding no further than 160. So this grant is the type of project that would fall right in the range between—it's in the area being discussed.

Senator PROXMIRE. In the marginal range.

Dr. WILLIAMS. Yes.

POLITICAL ORIENTATIONS

Senator PROXMIRE. I would like to discuss a few more specific grants with you. I think it is important to understand the rationale behind these grants in view of the fact that NIH is being forced to make some very tough choices in other areas. For instance, Dr. Goldstein told us yesterday that his institute was being forced to terminate funding for at least one of the two very successful Huntington's disease research centers at Johns Hopkins and Harvard.

Let me refer you to a 1-year award of $138,318 in direct costs for a project titled political orientations over the lifespan. The goal of the research, according to the Institute's summary statement, is "To estimate the degree of persistance and change in political attitudes over approximately 45 years and examine the sources of stability and change."

How will this work contribute to the health of older Americans?

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Dr. WILLIAMS. In my judgment, the value of that application relates to understanding attitudes and personality characteristics in general over the lifespan. We have a considerable difference of opinion in the psychological literature and psychological research on just what personality stability is like. A book has just been published by some of our own intramural investigators which shows a remarkable stability of personality and attitudes over the lifespan. My understanding of this grant is that it is addressing, using political attitudes as a measure of general social attitudes, the stability or instability of personality characteristics over time. This sheds light basically on how people function in terms of their personality over the lifespan. I don't know that this study necessarily had to be done with political attitudes, but it was the area of choice of that particular investigator.

Senator PROXMIRE. At any rate the award was for $138,000.

PRODUCTIVITY AND WORK

Last year Columbia received $85,397 for a project titled age and duration effects on career contingencies. This may not seem like a lot of money but it represents the yearly taxes paid by about 50 families of four earning $20,000 a year.

The purpose of the research is to analyze the structure of work careers in a large bureaucracy in the insurance and finance section of the economy. It is supposed to enhance our understanding of occupational mobility over the life course.

What would you tell those 50 families if they asked how this study would improve the health of the Nation?

Dr. WILLIAMS. I don't have any notes on that particular project, but from your summary, Senator Proxmire, the key point I detect is that this study has to do with productivity and working aspects. We need to know much more about the productivity, the work and retirement plans, views, and practices in our society as we move to a period when almost certainly it will be desirable for older people to continue productive employment.

Senator PROXMIRE. Do you think that has a direct effect on the health of older people?

Dr. WILLIAMS. Unquestionably it does. Also, and this may be stretching the point, I think we can expect older people, as time proceeds, to contribute more to tax income for our country.

CRIME AND THE ELDERLY

Senator PROXMIRE. Another study costing over $40,000 will consider the fear of crime among the elderly. The summary statement says the study is expected to yield very important results. How will the results be used?

Dr. WILLIAMS. The two highest worries of older people are loss of health and fear of crime. This fear of crime has had and does have many adverse effects on older people. Just the fear itself creates a much more limited environment and lifestyle.

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Senator PROXMIRE. All of us acknowledge that, Dr. Williams, but I wonder what this study will contribute to overcoming that fear or to ameliorating it?

Dr. WILLIAMS. If we can understand better what factors enter into the ways in which older people deal with the problem of fear of crime, we may be able to identify ways that will help ameliorate this problem in terms of what older people can do for themselves. This is not a universal answer; crime is a societal problem, not just a problem of older people. But if there are ways older people can learn to deal with this problem themselves, that will be a real contribution.

Senator PROXMIRE. There is no question about it, fear of crime is an abiding fear throughout our country and it is a terrible problem, but it would be helpful to know how this study would be put to use as specifically as possible. We might discover some very useful information, but the problem is——

Dr. WILLIAMS [interposing]. I will be glad to respond to the record.

[The information follows:]

FEAR OF CRIME AMONG THE ELDERLY

This study investigates the determinants of a major social problem—the fear of crime among the elderly. For example, how is the fear of crime affected by actual crime rates, the age composition of the city, or by the crime content of newspapers. Additionally, the study investigates how the fear constrains essential activities such as shopping or medical visits.

To the extent that fear of crime increases the social isolation of older people, and prevents them from leaving their homes for physical or social interaction, such fear may have an indirect effect on health and health care utilization. Thus it is important to understand the factors, both psychological and contextual, that aggravate this fear. Early findings from the study actually show that the climate of crime in a community is associated with the extent of fear among older people, in particular of major crimes such as murder and robbery. Prominent local news stories appear to be strongly related to the fear of crime. The content and contextual analysis of how the structural characteristics of cities—in terms of crime rates and economic, racial, and age composition—affect the fear of crime, may produce important clues to understanding financial anxieties among the elderly, migration decision, and the development of social isolation.

The results of this study will be widely disseminated. They may be expected to contribute to development of public policy, as well as ways to present crime information in the media less luridly; and to efforts to help the older age groups at highest risk to deal more effectively with related problems.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator PROXMIRE. Thank you. Thank you, Mr. Chairman.

Senator WEICKER. Thank you very much, Senator Proxmire. There will be further questions for response to the record. Thank you very much, Dr. Williams.

Dr. WILLIAMS. If I may, sir, I would like to leave two recent publications for you and I will be glad to furnish them to any other member of your committee. A survey of the Baltimore longitudinal study of

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aging and a book on the teaching nursing home as a new approach to geriatric research.

Senator WEICKER. Thank you very much. We will receive those books.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

FY 1986 PRESIDENT'S BUDGET

Question: I have questioned others on the impact of the OMB directive, and I will assume your Institute will suffer the same problems. However -- with our over-65 population making up 12% of our population and accounting for 30% of our health costs, isn't the administration sticking its heads in the sand by reducing the support for NIA medical research?

Answer: The administration has the difficult task of establishing national priorities and balancing the needs of all Federal programs against one another in the face of rising deficits and tight budgetary constraints. Medical research is a very important part of the Federal budget, but must be considered in conjunction with many other Federal priority areas.

NIA PRIORITIES

Question: If we were going to address the problem of an Aging America as seriously as the Department of Defense addresses the concept of Arsenal America, what kind of programs would you be asking for, and how much more funding would you need to get them started?

Answer: We believe we are presently addressing the problem of an aging America in a serious and responsible manner. In a time of constrained resources, difficult choices need to be made.

In recent years, it has become increasingly apparent that much of the morbidity and health care costs among the elderly are not caused by old age per se, but by specific disease processes which are potentially treatable or preventable. Probably the best-known example is Alzheimer disease. Others include falls, hip fractures, and osteoporosis; urinary incontinence; and cardiovascular disease.

In Alzheimer disease, additional resources would be used to fund more of the high quality applications not now fundable, and expand our intramural research in such aspects as the precise chemical nature of the abnormal proteins in the lesions in this disease, the possibility that they may consist of or be the result of infectious agents, the possibility of early diagnosis through specific antibody-identifiable substances in serum or spinal fluid, the possible role of changes in the blood-brain barrier in this disease, and the implications of intergenerational and familial relations on the care of persons with this disease. Assuming no resource constraints, further development of research efforts in this area would require an estimated $3,743,000 for the extramural program, $325,000 for the intramural Laboratory of Neurosciences, and additional staff. Extending the research base in the other areas outlined above would require $3,500,000 and supplemental staff to expand the intramural Behavioral Medicine Program.

In the area of molecular genetics, we would increase both our intramural and extramural research on genetic changes which may directly or indirectly affect the aging process, and research on genetic factors in the cause of major diseases in older people, specifically Alzheimer disease and osteoarthritis. This would include attempts to isolate and characterize the gene for Alzheimer

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disease. Increased funds for this research area would include $1,836,000 for the extramural program plus $400,000 and additional staff for the intramural Laboratory of Molecular Genetics.

In the area of the "oldest old," those aged 85 and older, we would speed up the analysis of the valuable data being obtained in the four elderly population longitudinal studies in Boston, New Haven, Iowa, and North Carolina; and also increase our funding of research grants dealing with physiologic and pathophysiologic changes in this group; and the extent of functional dependency, and possible ways to maintain health and effective functioning. We would enlarge our support for nutrition and exercise in the young-old as well as very old persons -- topics about which little is known but which clearly have important roles in health maintenance. Support for these projects would require additional staff and approximately $956,000.

There is increasing evidence that nutritional factors may play a role in degenerative diseases of aging, including osteoporosis (low calcium and vitamin D intake) and Alzheimer disease (trace metals). Zinc deficiencies in the elderly have been implicated in immune dysfunction leading to increased susceptibility to infection. However, definitive information on the role of these and other factors is lacking. In addition, dietary requirements for the aging population remain very unclear. NIA's estimated FY 1985 funding for research in this area is $2.7 million. To generate a "critical mass" of research on these problems, NIA is developing plans to establish aging nutrition research programs at academic research centers. To initiate these and other meritorious nutrition projects, NIA would require $2,300,000 and some additional staff in FY 1986.

Many studies document, but few attempt to explain, the paradox that women report more illness and health care utilization than men, yet outsurvive men on the average by 7 years. This difference in life expectancy is not invariant, but has been increasing rapidly throughout the century. By the year 2000 there will be an estimated 150 women for every 100 men at age 65 and over, a ratio that will rise to 250 to 100 at age 85 and over. These changes create a special opportunity for research on gender differences in health and longevity. The state of the science is now ready for such research. Longitudinal studies such as the BLSA have been recruiting women as well as men, and analytical techniques are now available for disentangling some of the gender differences from social, demographic, behavioral, and biological factors. An increment of $367,000 for extramural awards plus $700,000 and additional staff for the Baltimore Longitudinal Study of Aging would allow expansion of current studies in this area.

Finally, we would continue to increase our support for research training and career development, to provide as soon as possible the urgently needed academic leadership in gerontology and geriatrics throughout our nation. An additional $1,040,000 for 14 competing research career awards and $953,000 for 43 extramural training positions, plus $375,000 to support additional intramural training positions would aid in achieving the goals established by the DHHS Task Force on Training in Geriatrics and Gerontology.

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ALZHEIMER DISEASE RESEARCH CENTER

Question: Alzheimer disease has become one of this committee's highest concerns and research priorities. It creates a tremendous burden on family and friends and is responsible for generating tremendous costs.

Last year to help mount a significant research effort in this area we provided funds to the National Intitute on Aging for five additional centers for research on Alzheimer disease. You are only going to fund three centers. What specifically will be the impact on the progress of research on Alzheimer disease if the additional centers remain unfunded?

Answer: Solution of the Alzheimer disease problem requires massive multidisciplinary attack by the very best medical and basic scientists of this country. The five ADRCs funded in FY 1984 and the three to be funded in FY 1985 will provide the basic groundwork for a multidisciplinary effort to accomplish this task. Two additional ADRCs will be funded in FY 1986, a delay of only a few months.

ALZHEIMER DISEASE RESEARCH

Question: How much of your current budget is allocated for all Alzheimer research?

Answer: When the multiyear funding is taken into account, we estimate the FY 1985 budget for Alzheimer disease at $26,921,000. An additional $2,500,000 of FY 1985 funds would be used to forward fund the three FY 1985 competing ADRCs for one year.

Question: Give us some examples of projects or proposals that have important new ideas that will go unfunded under this year's budget request.

Answer: At present the NIA has a significant number of scientifically very high quality proposals that cannot be funded. These projects address some of the most crucial scientific puzzles relevant to Alzheimer disease, including:

- the role of environmental toxins such as aluminum in causing Alzheimer disease
- new types of virus which has special affinity to nerve cells in the brain and their potential for causing human brain diseases in old age
- mechanisms by which patients with degenerative dementia may be able to compensate for some of the disabling aspects of the disease.
- the role of biochemical agents inside nerve cells in forming abnormal proteins which cause cell death
- immunological methods to detect the existence of major protein component of cerebrovascular amyloidosis in Alzheimer disease. This study potentially could provide a very sensitive and precise tool for diagnosing Alzheimer disease in its early stages

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RESEARCH ON AGING

Question: We are aware of the fact that basic research on the nature of the aging process is a relatively new area of research. Could you please tell us the status of that research?

Answer: NIA has a wide spectrum of research to delineate the mechanisms of aging at the molecular, cellular, and organ levels. Some examples of current research include studies of oxidative damage to proteins and nucleic acids; rearrangements of DNA during aging; identification and characterization of genes controlling aging; changes in the extracellular matrix during aging, response of cells to oxidative stress; repair of DNA; control of cell proliferation, and similar opportunities.

LIFE EXPECTANCY

Question: Have you found anything that suggests the possibility of extending life beyond current life expectancy?

Answer: The most well-documented means of increasing lifespan in experimental animals is dietary restriction -- diminishing average daily caloric intake, either throughout life or beginning in adulthood. As demonstrated by numerous researchers, this technique can increase average and maximum lifespan of laboratory rodents by approximately 40 percent. This type of dietary restriction not only extends the lifespan of the animals, but also delays or prevents the onset of many major age-associated diseases including heart disease, cancers, and kidney disease.

At this time, we should probably remain skeptical about the potential benefits of dietary restriction in humans. The effects may be unique to rodents, or related to special laboratory conditions that would not apply to people. On the other hand, dietary restriction may actually slow basic aging processes which control the rate of development of cancer, cardiovascular disease, and other disorders.

Because the ability to slow these processes would have enormous implications for health and longevity, we believe that more intensive research on dietary restriction is needed. We need to know whether dietary restriction extends lifespan in other species besides rodents, and the mechanisms responsible for its effects. The latter research is very likely to increase understanding of aging processes, whether or not dietary restriction is beneficial to humans. This understanding could in turn lead to other practical ways of retarding fundamental aging processes in people. For these reasons, NIA has begun a program to encourage research in this area.

TRAINING

Question: Are we training enough scientists to provide for the expected expansion of research opportunities in gerontology?

Answer: The Report on Training and Education in Geriatrics and Gerontology, issued February 1984, estimated that 1,300 physician faculty members in clinical departments and 1,300 other faculty for all of our nation's medical schools will be needed to provide

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academic leadership in geriatrics and gerontology in the years to come. This would require more than a doubling of present efforts. To reach half of the goals by 1990, and the full numbers by the year 2000, about 300 new, trained faculty members for medical school need to be turned out each year. At present, the National Institute on Aging is supporting training of 70-90 new potential faculty members each year for basic and clinical activities through intramural and extramural programs, including fellowships and academic career development support. For FY 85, NIA plans to devote about $10 million in support of training programs, an increase of about $3.67 million over FY 84. This would allow for an increase in the number of new trainees from 32 in FY 84 to approximately 87 in FY 85. We will support 44 new trainees in FY 86. The NIA, as a member of the HHS Task Force on Enhancement of Training in Geriatrics and Gerontology, will continue to work in concert with the other agencies such as the National Institute of Mental Health, the Veterans Administration, the Health Resources and Services Administration, and the Administration on Aging to promote the initiatives outlined in the above-referenced report so that all health professionals can be prepared for care of older people, and so that research in aging can be advanced.

FUTURE HEALTH CARE NEEDS

Question: Most of the projections about the health care needs of the elderly in the year 2000 are based on today's knowledge of medicine and, where possible, on expected advances. What are we really looking at -- in the area of cost of care -- if Government funding of biomedical research fails to expand to meet the research opportunities created by new findings?

Answer: In 1985, the total health care cost to the Nation was in excess of $320 billion. The nursing home cost alone was around $27 billion. Although the elderly constitute nearly 15 percent of the population, as a group, they account for nearly 40 percent of all health expenditures. It is expected that, by the year 2000, the proportion of the elderly in the U.S. population will double. The health care cost is expected to increase exponentially. For example, the nursing home costs alone are expected to exceed $100 billion.

Today, biomedical research is on the threshold of being able to develop the necessary biomedical technologies to prevent, ameliorate, or treat many of the costly debilitating conditions of the aged. It should be possible to target pharmacological agents more precisely to the conditions in these patients. Through computerized imaging techniques, it should be possible to diagnose pathological conditions at early stages of disease. It also appears to be within the realm of possibility to repair damaged parts of brain through transplant technology. It is expected that these and other advances will reduce hospital stays and thus reduce the cost of health care.

ALZHEIMER DISEASE RESEARCH

Question: Give us a brief overview of what has been accomplished during the past five years in Alzheimer disease?

Answer: Scientific achievement in Alzheimer disease research in recent years has been truly remarkable. In a very short time we have

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progressed from almost total ignorance and despair to a point of great expectations and hope of conquering the disease. Recent achievements include:

- o More accurate and early diagnosis of the disease. The accuracy has improved from 60 per cent to 90 per cent in most major medical centers.
- o It has been established that the disease is associated with biomedical defects in brain cells.
- o Specific brain areas affected by the disease have been identified.
- o Instruments for detecting early signs of brain damage have been developed and are being improved upon.
- o Several hypothesis as to what causes the disease have been proposed and are being tested.
- o Various pharmacological agents are being tried, in animal studies, to improve memory loss. Certain agents are being tried in human subjects with Alzheimer disease.
- o Work with family members on how to reduce the burden of the disease has begun and methods of providing relief to families have been developed.

Question: What are some of the important scientific opportunities that are ready to be exploited with regard to Alzheimer disease?

Answer: The most important scientific opportunities that are ready to be exploited with regard to Alzheimer disease include:

- o Development of more accurate and sensitive diagnostic instruments such as PET and NMR
- o Delineation of pathophysiological brain areas and neurotransmitters involved in Alzheimer disease
- o Analysis and application in diagnosis of abnormal proteins found in Alzheimer disease
- o Definition of the chemistry of abnormal proteins found in the lesions of Alzheimer disease such as paired helical filaments, microtublers and other cytoskeletal elements
- o Steps to locate, isolate, clone, and characterize genes involved in familial Alzheimer disease
- o Exploration of the role of viruses as possible etiologic agents in Alzheimer disease

Question: How much of your current budget is allocated for Alzheimer disease?

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Answer: Our current estimated FY 1985 budget for Alzheimer disease is $26,921,000.

Question: What additional resources do we need to take advantage of these scientific challenges?

Answer: We need to create an appropriate environment where the biomedical, social, behavioral and economic aspects associated with the disease can be studied in an integrated multi-disciplinary fashion. The NIA Alzheimer Disease Research Centers provide such an environment, but cannot alone adequately address the full spectrum of problems associated with this disease. Individual high quality research projects are also an essential ingredient in the fight against Alzheimer disease. We currently have 5 such proposals related to Alzheimer disease research with priority scores of 200 or better which fall outside the funding range for 1985. To fund these awards would require aproximately $1,027,000.

Question: In terms of health care costs of the elderly, how do you rank Alzheimer's disease?

Answer: Alzheimer disease is estimated to cost the American public between $28 and $35 billion per year. Alzheimer disease and related dementing disorders of the aged are the most expensive health care issue for the elderly. This is true because of the large number of the people involved, the long clinical course of the disease (10 years on the average and up to as long as 20 years) and the labor intensive care required for the disease. But the most important cost is the suffering and pain to the families of the victims which cannot be measured in dollars.

DISEASES AND DISORDERS OF THE ELDERLY

Question: What are some of the other costly problems (i.e., diseases, disorders) of the elderly?

Answer: Several health problems of the elderly create very large health care costs: These include:

Urinary Incontinence: Urinary incontinence is a major contribution to disability and institutionalization among older persons. Community-wide studies indicate that 10% or more of persons aged 65 and older have some problem with urinary incontenence, i.e., 2.7 million or more in the United States. At least 500,000 American elderly may suffer incontinence severe enough to seriously restrict their daily activities. The cost of dealing with urinary incontinence in nursing homes has been estimated at approximately $1 billion per year in the U.S. In addition, incontinence is responsible for substantial costs among the home dwelling elderly, but firm figures are not available for this population.

Osteoarthritis: Sixteen million Americans, most of whom are elderly, suffer from osteoarthritis. Osteoarthritis, which is the commonest form of arthritis, is responsible for substantial costs for health care and for institutionalization of severely disabled patients. The annual costs associated with arthritis of all types are approximately $7.5 billion. Specific figures for osteoarthritis are not available, but it seems likely that it is responsible for at least $2.5 billion, and possibly much more.

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Falls, Hip Fractures, and Osteoporosis: Osteoporotic fractures and other injuries due to falls are a major cause of death and disability in the elderly. Hip fractures represent the most important combined outcome of osteoporosis and falling. At least 200,000 Americans suffer hip fractures each year. Most hip fractures occur in white women and 70 percent occur after age 75. Fifty to sixty percent of those who were previously independent become totally or partially dependent. Total medical care costs for hip fractures are estimated to be in excess of $2 billion a year.

Isolated Systolic Hypertension (ISH): ISH is a form of high blood pressure which is found predominantly among the elderly. It occurs in up to 20 percent of older Americans. Persons with ISH are at least three times greater risk of cardiovascular disease and stroke, compared to people with normal blood pressure. Thus, for example, ISH may be responsible for as many as 90,000 strokes per year. The direct costs of these strokes alone are at least $1 billion. To these must be added the unknown indirect costs, and costs of other cardiovascular diseases associated with ISH.

Other problems that produce a great degree of disability in the elderly are problems of the circulatory system, disorders of the musculoskeletal system, decline of immune function, and neoplastic disorders. In addition to further understanding of these disorders, better understanding of the psychosocial and biomedical factors leading to entry into long-term care institutions is needed if costs of care are to be reduced. Additional contributions may be made through better understanding of the health maintenance and disease prevention practices in the middle and later years, including optimal nutrition and the role of exercise.

HEALTH AND EFFECTIVE FUNCTIONING

Question: You have said that the primary goal of the NIA is to extend the healthy years of middle life, thereby reducing the impact of the aging process. Can you give us examples of research that you are supporting that may accomplish these aims?

Answer: NIA has a major program on maintaining Health and Effective Functioning in the Middle and Later Years. A wide range of studies is demonstrating 1) that many beliefs of inevitable and universal decline with aging are false; 2) that appropriate health promotion strategies, many still needing detailed specification, can prevent or postpone many age-associated deficits; and 3) that certain old-age disabilities, when they do exist, can be reversed or alleviated.

Contrary to widespread medical and popular belief, few healthy individuals up to age 60, and less than half even at age 80, show reliable declines in cognitive test performance as they grow older. Among those 65 and over, only 5 percent are in nursing homes; and while some 80 percent report having some chronic condition, fewer than 1 in 6 say they are thereby prevented from carrying on their normal activities. However, such facts are little recognized, and false stereotypes of inevitable aging decline must be fully documented to correct current practices by physicians and patients to take the ills of older people for granted, leaving them untreated.

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NIA research on prevention of old-age decrements includes studies examing the mechanisms through which the familiar life-style factors affect health: including nutrition, exercise, non-smoking, mangement of stress, and social support. For example, one study which has followed a sample of 7,000 people for 17 years shows that the increased mortality associated with several social and behavioral risk factors -- smoking, physical inactivity, substantial deviation from ideal weight, low life satisfaction, social isolation -- persists even among those who have reached the ages of 70 or over. The goal of continuing research is to define the extent and nature of life style changes which can be properly recommended to the elderly, and to test means of influencing attitudes and life styles to produce these changes.

Many studies already indicate the potential for reversing or alleviating old age disabilities. For example, intellectual decline with aging, when it occurs, can often be slowed or reversed by relatively simple training interventions. A distinction must be made here, however, between "benign" intellectual decline and decline due to Alzheimer disease or other dementing diseases. Research has demonstrated that the performance of older persons on intelligence tests improves with added practice, with instructions about strategies for approaching the problem, and with incentives to increase motivation and attention. Data show that training improves fluid intelligence, conscientiousness, and persistence; lowers levels of anxiety; and enhances such aspects of physical well-being as cardiac function. It has also been demonstrated that older people can, and often do, learn to compensate for declines in reaction time, memory, and other age-related deficits by using mnemonic strategies or by exercising great care and persistence.

In addition to findings such as these, research on rehabilitation from illness, bereavement, the experience of the menopause, and other topics are yielding important findings related to health and effective functioning in the middle and later years.

Question: If the funding were available, how much more would you need to support these programs at measurably higher levels?

Answer: As noted above, NIA-supported studies are beginning to show how even greater proportions of the elderly can maintain the vigor, health, and productivity of the middle years. Additional research is required along the lines already established, and should be strengthened in such areas as: health attitudes and behaviors, the role of exercise and optimal nutrition, life style changes, cognitive functioning, biopsychology, housing and living arrangements, and productivity at work. Current funding for this program, which amounted to less than $7 million in 1984, should be at least doubled by FY 1987 in order to support the excellent research already proposed. We would also need a small accompanying increase in staff.

IMPACT OF FY 1985 GRANT REDUCTION

Question: The FY 1985 appropriation for NIA emphasizes two important areas of research, molecular genetics and the population over 85. How will the President's proposals for 1985 and 1986 affect your ability to fund research projects in these new areas?

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Answer: Four very good proposals in the area of molecular genetics have been reviewed and would have a good chance of being funded at the FY 1985 Appropriation level of 6500 competing grants. An additional four proposals would have some chance of funding. Under the President's budget, none of these eight are likely to be funded.

The reduction in FY 1985 competing grants from the Appropriation level will also affect the initiative on the Oldest Old, which is presently represented by only three funded projects. An important descriptive study of this population with an excellent priority score cannot be funded at the reduced level. Several meritorious research projects on clinical problems of the very old will not be fundable, including studies on causes of falls in nursing home patients and side effects of testosterone deficiency.

FTE REDUCTIONS

Question: What will be the impact of reducing FTE's on research in these areas?

Answer: Develpment of new research programs is a time consuming activity which requires considerable thought and concentration on the part of our scientist administrators. FTE reductions will, therefore, slow the development and implementation of the new extramural priorities in molecular genetics and the oldest old. For example, staffing for the new Laboratory of Molecular Genetics has been reduced to one FTE in FY 1985, and full implementation of the laboratory will be deferred. In the area of the oldest old, the analysis, and reporting of data which have now been obtained in the Established Populations for Epidemiologic Studies of the Elderly will have to be spread over a longer time span than would otherwise be the case.

IMPACT OF FY 1985 GRANT REDUCTION

Question: The OMB directive effectively reduces the number of approved grants that will be funded by your Institute. Will important and necessary continuing research be stopped, and will new research proposals that have excellent priority scores go unfunded?

Answer: A number of important ongoing projects in the areas of molecular genetics and Alzheimer disease, which are competing for renewal funds in FY 1985, would have been included at the FY 1985 Appropriation level, but will not fall within the funding range outlined by the President's budget. There are in addition a number of new applications in these fields that are in a similar state. In the behavioral sciences area, an important descriptive study of a population of the oldest old will not be funded; nor will a number of other highly meritorious applications such as a project on abuse of elder parents in the home, and another which would identify whether certain living arrangements are placing some older adults at risk of malnutrition. Each of these projects has a priority score below 180.

Question: What impact will this have on your Institution?

Answer: For the last several years, NIA program staff has

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devoted considerable effort to the development of aging research capability in such critical areas as molecular genetics, molecular biology, Alzheimer disease and the oldest old. These efforts included holding conferences to summarize current research status and needs, presentations and seminars at scientific meetings to encourage applications and the issuance of program announcements to inform the scientific community of NIA interaction and support for research in these areas. These activities are resulting in significant new applications and research interest on the part of "cutting edge" scientists who have not previously applied their skills to research on aging. Important scientific opportunities are, therefore, ready to be undertaken. The reduction will delay pursuit of these opportunities and may lead to a loss of scientific manpower in aging research as scientists turn to other fields of endeavor.

GERIATRIC RESEARCH

Question: You have stated on several occasions that by the year 2020 the population over 65 will double and that the year 2000 the population will almost double. In view of these statistics, what programs are your Institute involved in now that will help meet this challenge?

Answer: For the past 7 years we have developed studies of populations 65 and over in order to better understand the natural history and evolution of this population. The major questions relate to the issue of providing a maximum number of healthy years after age 65 and a minimum number of years of ill health and disability. We are developing basic information in four populations over age 65 in order to more clearly define these patterns and monitor their changes over time. The Established Populations for Epidemiologic Studies of the Elderly (EPESE), has been initiated and we are now longitudinally following approximately 16,000 elderly Americans. The populations are both urban and rural and in one we are oversampling Blacks. In addition to these data, we are following another 8,000 elderly who were initially examined in the National Health and Nutrition Examination Survey I (NHANES I) between 1970 and 1974. Further studies involve the longitudinal investigations conducted by NHLBI in Framingham and in Honolulu.

The Alzheimer Disease Research Centers are expected to contribute substantially to the future well being of the elderly as they develop methods for diagnosing and treating Alzheimer disease and other dementias of aging. The NIA initiative in training future researchers and academicians in geriatrics and gerontology is also of crucial importance in assuring that quality of life is maintained into old age.

NIA's Teaching Nursing Home (TNH) program is designed to develop the scientific data needed for better treatment and prevention of Alzheimer disease, arthritis, osteoporosis, and other disorders which are responsible for institutionalization of older people. These projects have already been responsible for several important research findings on these disorders. These projects have also helped to improve quality of geriatric education and care. They have also helped increase interest in geriatrics at medical centers throughout the U.S. Research interest in the TNH program remains high.

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Another NIA program in this area concerns health and effective functioning in the middle and later years of life. Here the emphasis is on sustaining the vigorous health, effective functioning, and productivity of the middle years through research on such topics as: accident prevention; coping with stress; health attitudes and behavior; patterns of eating, drinking, smoking, and exercising; psychosocial factors in senile dementia, menopause, hypertension; and those psychological and socioenvironmental factors that may affect major physiological systems (neurochemical, immune, and endocrine). Research has already demonstrated, for example, that intellectual decline can often be slowed or reversed by relatively simple training interventions; that older people can often learn to compensate for declines in reaction time, memory, and other age related deficits; that particular styles and sizes of type can facilitate reading, and improved environmental design can offset inability to see large objects in low contrast; and that among the frail elderly, even those in nursing homes, a heightened sense of personal control exerts an influence on morbidity and mortality.

A new initiative focuses on the oldest old, those over age 85. Although little had previously been done in this area, a few ongoing studies deal with morbidity, mortality, and causes of death and also seek answers to such questions as: What will the very old of the future be like--in health, functioning, values and attitudes? What changes will be made in social structures to accommodate their needs and utilize their potential contributions? Since the quality of data on the oldest old is sparse and of poor quality an important component of this initiative is the improvement of development of data on this population. Early findings suggest that there is no end yet in sight to the improvements in life expectancy at the older ages.

PREVENTION

Question: In a speech before the American Pharmaceutical Association Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: Prevention has always been a central concern of the National Institute on Aging. NIA's long-range program of research on prevention includes research on such topics as: a) How to maintain vigorous health, effective functioning, and productivity through the middle years and into old age; thus to save costs of economic inactivity and nursing home and medical care; b) How people can be encouraged to adopt healthy behaviors and health practices after they have reached old age; c) How to restore functioning and reverse common forms of disability in old age, in order to reinstate older people in productive roles, and to prevent institutionalization in nursing homes, d) How to compensate for age-related deficits and impairments; and e) How to explain and perhaps offset the excessive rates of mortality among minorities and the economically disadvantaged.

A new NIA initiative in behavioral geriatrics research is specifically concerned with extending scientific understanding of: how older people's health behaviors and attitudes are formed under varying social conditions, how they relate to health promotion and

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disease prevention, and how they can be modified as relevant new scientific knowledge is developed. Under this general initiative, several longitudinal studies are being conducted to identify social and behavioral factors associated with reduced morbidity and mortality in old age. Other studies are examining antecedents and consequences of different types of health care behaviors--ranging from self-care to formal health care utilization. Another set of studies is developing and testing socio-behavioral strategies for promoting desirable health attitudes and behaviors and eliminating unhealthy ones.

In the biomedical field, research supported by NIA on health promotion and disease prevention includes studies focused on exercise physiology research and nutrition research. The elderly represent a special physiological category and need to be studied separately rather than to be understood by extrapolation. With this in mind, we are attempting to assess for both elderly men and elderly women whether and under which circumstances the recommendation of physical activity is medically reasonable; whether, indeed, biological adaption to physical training is possible; and how, if at all, such training translates into healthy existence. Recently published studies of relatively short duration, indicate favorable increases in aerobic capacity and improvement in blood lipid profiles in previously sedentary older persons who undertook an exercise program. These studies need to be extended in number and in duration.

Nutrition may play an important role in preventing diseases and maintaining good health in late life. NIA supports research on the role of calcium and vitamin D in preventing osteoporosis and hip fractures, nutritional factors affecting Alzheimer disease, the potential of zinc supplementation for improving immune function and disease resistance in the elderly, and many other topics. NIA also supports epidemiologic studies which suggest that many elderly may have serious nutritional deficiencies. The results of NIA-supported research to date indicate the substantial improvements in health of the elderly could result from research in this area and transmission of research results to the public.

Question: What percent of your budget is directed to preventive research?

Answer: Based on the definition used throughout NIH, approximately 52 percent of the total NIA budget is either primarily or indirectly related to prevention. This includes a wide range of research which has as its major goal the maintenance of health and effective functioning into the later years of life.

INFORMATION DISSEMINATION

Question: How are the results of this research being translated into useful public information?

Answer: The NIA translates its research information through many channels. Our audiences include older citizens, physicians, and related health care providers. The Institute tailors its materials for each of its publics. The major objective of our public education program is to inform and educate all Americans, particularly the elderly, about health practices that can reduce their risk of illness

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and can assist them in maintaining good health and independence as long as possible. The most visible efforts in this area are the widely acclaimed Age Pages (a series of fact sheets) and the "Help Yourself to Good Health" campaign. Age Pages address issues ranging from finding good medical care to exercise and nutrition. The emphasis is on a simple easy-to-read format with action-oriented health hints. Through the efforts of several voluntary organizations, selected Age Pages are available in Spanish and Chinese. Recognizing that informed self-care is the founda- tion of health maintenance for all, not just the young, Pfizer Pharmaceuticals has sponsored a series of health-promotion activities, Help Yourself to Good Health, with the NIA. This effort began as part of a nationwide touring exhibition, sponsored by the American Association of Retired Persons, that visited shopping malls across the country. The centerpiece of the campaign is the publication, Help Yourself to Good Health, a collection of 29 Age Pages. Pfizer has made this material available free of charge to well over 1/2 million people. Although these materials were developed as one of our means of communicating directly with the public, they have been embraced by the medical community as tools for their communication with the elderly. The State of Georgia will be distributing Help Yourself to Good Health to all of its physicians during Older Americans Month. In an effort to transmit current knowledge on the prevention of osteoporosis, a leading cause of hip fracture in older women, the NIA is collaborating with the American Association of Retired Persons in a multi-media campaign aimed at making women cognizant of the need to maintain adequate intake of calcium regardless of age.

SCIENTIFIC OPPORTUNITIES IN ALZHEIMER DISEASE

Question: In comparing those Alzheimer disease projects that are selected for funding, by your Institute, with those that are not being funded, are we missing any important scientific opportunities?

Answer: While significant advances are being made, we are missing a number of scientific opportunities. Important projects relevant to Alzheimer disease which we have on hand and cannot presently fund include studies on the role of environmental toxins such as aluminum in Alzheimer disease; an unusual virus which has special affinity to nerve cells in the brain and its potential for causing human brain diseases in old age; a mechanism by which patients with degenerative dementia may be able to compensate for some aspects of this disabling condition; and the role of biochemical agents inside nerve cells in forming abnormal proteins which cause cell death. Other unfunded high quality propsals include anatomical and physiological studies of the normal aging process and pathological mechanism of dementia and studies of immunological methods to detect the existence of major protein components of cerebrovascular amyloidosis in Alzheimer disease. The latter study has the potential to provide a very sensitive and precise tool for diagnosing Alzheimer disease in its early stages

ALZHEIMER DISEASE RESEARCH CENTERS

Question: What have you accomplished with the funds provided to your Institute for Alzheimer Disease Research Centers during the past year?

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Answer: In FY 1984, five Alzheimer Disease Research Centers (ADRCs) were established. These centers are taking steps to develop collaborative studies such as common data gathering protocols and the design of multi-center projects. During FY 1985 NIA expects to fund three additional ADRCs, plus another two during FY 1986. Although the five initial ADRCs have been in operation for only a few months, they have begun to produce important scientific knowledge. At one of the centers, it has been found that through nuclear magnetic resonance (NMR) imaging very early signs of small strokes or multi-infarct dementia can be detected and distinguished from Alzheimer disease. This will enable physicians to institute appropriate treatments, thus preventing further deterioration. At another center evidence that some forms of Alzhimer disease are due to genetic factors is being confirmed and extended. At a third center, certain similarities between Alzheimer disease and Pick's disease were identified. In addition, the chemical make-up of senile-plaques has been identified. These are just a few illustrations of the extensive multidisciplinary research that is underway.

Question: What are your future plans for additional Alzheimer disease research centers?

Answer: At present we are reviewing twelve competing applications. We expect to fund three new ADRC's during FY 1985 and two more during FY 1986.

Question: What do you expect to accomplish with the research center mechanism which cannot be accomplished by other funding mechanisms?

Answer: The comprehensive research center mechanism will enable NIA to accomplish several goals, which otherwise cannot be acheived. These include:

- Multidisciplinary research including biomedical, behavioral and social sciences - all aimed at enhancing our knowledge of how to detect the disease, what causes it and how to treat it.

- It will enable us to create large pools of crucial clinical data on Alzheimer disease and its course which will help identify risk associated with the disease.

- As promising therapeutic agents become available, the centers will become increasing involved in clinical trials to test their effectiveness.

- It will aid in the creation of a network of scientists and care providers who work together for a common goal and communicate their findings to the public and professionals. These centers will serve as training sites for investigators and practitioners.

- The centers will serve as regional resources for consultation on diagnosis and treatment.

- By giving national visibility to the disease at major medical centers, other medical disciplines will become more involved in Alzheimer disease research.

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COORDINATION OF ALZHEIMER DISEASE

Question: Do you have any plans to establish links with such centers in other countries to facilitate international cooperative studies of Alzheimer Disease?

Answer: The NIA is a World Health Organization (WHO) coordination center for health of the elderly. The Director of NIA has met with the leaders of WHO and has begun laying the foundation for cooperative studies on Alzheimer disease. The NIA has already received applications for such international cooperative studies from other countries. These proposals are under review. The NIA has taken the lead in organizing an international conference for the purpose of establishing international standards for accessing and diagnosing Alzheimer disease and for cognitive functioning.

Question: What multi-disciplinary programs have you established to solve this problem?

Answer: Alzheimer disease does not recognize regional, national, ethnic or socio-economic boundries. The disease has significant implications for many scientific disciplines because it is several entities at the same time. It is a neurological disease; it is a psychiatric disorder; it is a social and psychological problem for the victims' families; it is an economic and a services delivery problem. The broad legislative mandate of NIA has enabled us to establish research programs through our Biomedical and Clinical Medicine Program, Behavioral and Social Sciences Program and Biometry, Epidemiology and Demography Program to attack the problem in a multi-disciplinary fashion. The Alzheimer disease research centers are a major multidisciplinary effort. We collaborate fully in these activities with the other institutes of NIH, with the National Institute of Mental Health, and with other Federal agencies, including the continuing activities of the Secretary's Task Force on Alzheimer disease.

ALZHEIMER DISEASE RESEARCH CENTERS

Question: Five specialized research centers ($3.5 million, FY 1984 Appropriations) for research on Alzheimer disease have been established. Was the $3.5 million sufficient to equip, staff, and maintain these center?

Answer: The five applicants for ADRCs which were funded in FY 1984 originally requested approximately $5.5 million to staff, equipment and maintain their centers. In order to comply with the available $3.5 million dollar funding level, the NIA requested that all five centers trim and cut back their proposed projects.

Question: Are the centers using any of the $3.5 million to study the impact on the families of Alzheimer victims or to help provide any services to the families?

Answer: All of the five centers have a component that will relate to the family members. The guidelines for the centers directed each center to have a formal tie to local family member groups and/or the Alzheimer Disease and Related Disorders Association. The centers are to serve as channelling for information

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and referral. In the future years this component will be strengthened.

ADMINISTRATIVE COST DECREASES

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: Administrative costs associated with these mechanisms can be reduced in a number of ways. One possibility is to limit the areas of research for which certain types of applications will be accepted. For example, when the NIA issued the announcement of its small grants (R03) program, applications were accepted only in such specific research areas as animal models, exercise physiology, senile dementia of the Alzheimer type, and health and effective functioning. Similarly, Teaching Nursing Home and Alzheimer Disease Research Center applications had to meet very demanding criteria to be considered, as do all contract proposals.

These procedures limit to some degree the total applications and proposals received, and thereby reduce the potential grant and contract work load -- including number of total site visits and outside site visitors needed, time involved in the review process itself, and associated costs such as printing of applications and summary statements. Another way for reducing administrative costs is to withdraw some Requests for Applications, such as was done for the Geriatric Medicine and Dentistry Academic Awards last year and will be done for the small grants program this year. Administrative cost may also be reduced by reducing the size of at least some site visit teams thereby reducing travel costs and, in the case of outside reviewers, fees of up to $100 per day.

ADMINISTRATIVE EFFICIENCY

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: In FY 1984, the NIA undertook a thorough organizational assessment effort with the aid of the NIH Division of Management Policy and outside consultants. The effort focused on five key goals for improved management:

- Increased awareness and understanding among all NIA managers and staff with regard to such things as how to best manage and organize the Institute; the roles and responsibilities of NIA managers, staff and organizational components; and what decisions must be made to change and improve the management and organization of the Institute.

- Development of a comprehensive profile of NIA in terms of its areas of strength and areas in need of improvement.

- Collection of baseline data against which to measure and evaluate future efforts to enhance effectiveness in the Institute.

- A catalog of specific problems or conditions which NIA managers and staff view as preventing them, individual work groups, and/or

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NIH from being as effective, productive and innovative as possible.

- Development and implementation of agreed upon changes and improvements.

The assessment project was conducted using two standard survey tools (i.e., the University of Michigan, Institute for Social Research "Survey of Organizations" and the Myers-Briggs Type Indicator assessment of management and leadership styles) and a series of individual and group interviews. The collected data was analyzed and fed back to all NIA staff. The NIA is now in the process of developing and implementing proposals and action plans for bringing about agreed upon changes and improvements. A follow-up of the assessment project and its results is planned.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: The NIA has recognized for some time the need for improved communications among the various programs, offices, and staff of the institute. The anticipated goals of such an improvement included not only communications per se, but increased office productivity as well. To this end, a study was conducted by the NIH Division of Computer Research and Technology (DCRT) during the fall and winter of 1984 to determine the feasibility of an integrated communication system utilizing small personal computers. The study indicated that the NIA should pursue a strategy of Institute-wide office automation, to be phased in over a 24-month period.

The NIA is currently in the early stages of developing the proposed Integrated Communication System (ICS). The ICS has a broad array of possible applications ranging from office automation, including word processing and files maintenance; electronic mail and calenders; program and office mangement; access to various internal NIA grant files and DCRT files, as well as major national data files such as MEDLARS, TOXLINE, etc.; and communication between off-campus NIA components and the main NIA component on the NIH campus. Once designed and implemented, this system should facilitate productivity of Institute staff, make available an increased level of information not presently disseminated, and provide the ability to manipulate an increased volume of data not presently possible. It is expected that, when fully implemented, it will also aid in decreasing overall administrative costs.

In addition to the ICS, certain reorganization steps and reassignments of function to increase efficiency are also being taken.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: The review process is controlled by NIH-wide guidelines. Equitable and complete review of research proposals will not be affected by administrative costs decreases.

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Questions Submitted by Senator William Proxmire

NIH STUDY SECTIONS

Question: Dr. Williams, the studies I have mentioned today were reviewed by either the Human Development and Aging Review Group or by the Social Sciences and Population Study Section. Please tell us for the record what percentage of the applications approved by these two sections received Federal funding in fiscal year 1984 and compare this with the comparable percentage for your Institute as a whole.

Answer: Of the applications approved by the Human Development and Aging and Social Science and Population study sections, 50.7 percent and 16.7 percent respectively were funded compared with an overall NIA award rate of 28.1 percent. However, it should be noted that the Human Development and Aging review group has a particularly low approval rate (i.e., 51.7 percent of applications reviewed in comparison to the overall NIA approval rate of about 75 percent). When total applications received are compared with total applications funded, the Human Development and Aging study section funded 26.2 percent of all applications received compared with 21.1 percent for NIA.

PRIORITY SCORES

Question: Can you tell us, for the record, if necessary, the priority scores of the five projects funded over the past months receiving the highest number of priority points?

Answer: The five projects with the highest number of priority points, i.e., the least good priority scores, which were funded in FY 1984 are listed below.

Grant	Priority Score	Award Mechanism
1	250	Small Business Innovation Research
2	286	Small Business Innovation Research
3	394	Small Business Innovation Research
4	220	Research Center Grant
5	208	Research Center Grant

For comparison, the five highest priority scores for individual investigator-initiated grants (R01s) awarded in FY 1984 ranged from 178 to 180.

SMALL BUSINESS INNOVATION RESEARCH AWARDS

Question: Let me refer to one more grant. This one is titled "Applications of Information Technology for the Elderly." It was made to Senior Software, Incorporated, and the money will be used to examine the potential use of personal computers to broaden the elderly's range of experience and enhance psychological well-being. The project resume says the project may have good commercial potential. The one year direct cost of the project is about $50,000. If this venture has good commercial potential, why isn't it being funded by the private sector?

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Answer: The project is a Phase I (pilot feasibility study) Small Business Innovation Research Award mandated by Congress. The purpose of this award is a pilot research project to study the potential application of personal computer technology to maintaining and improving the cognitive functioning of the elderly. If feasible, a request for Phase II support to model a program that would attract private support for its commercialization will be made.

Question: This project had a priority score of 286. Isn't this an exceptionally low priority for a funded project?

Answer: NIA research project grants were funded to a priority score of 180 in FY 1984. In this sense, the project you mention was well below the normal funding range. However, the Small Business Innovation Award competes for a Congressionally mandated set-aside of funds independent of the pool of funds for regular NIH research grants. The priority score for this project falls well within the range of priority scores for other NIH SBIR awards supported during the time when this application was funded.

Question Submitted by Senator Daniel K. Inouye

TEACHING NURSING HOMES

Question: The Committee would appreciate learning the extent to which the NIA's teaching nursing home initiative is currently supporting projects from schools of nursing. What are the NIA's plans for expanding this program this year and to what extent will faculty from schools of nursing be actively involved in these new projects.

Answer: Schools of nursing are involved in the administration of all seven NIA Teaching Nursing Homes (TNH). At most of these projects, nursing school staff are responsible for developing patient registries and data bases which are a central resource for TNH research. Nursing school staff are also directly involved in several TNH research projects, including two studies of factors leading to falls among nursing home patients, and a study on the impact on patient care of research in nursing homes.

We believe that a modest expansion of the TNH program would be useful. Since its start in 1982, the program has produced important research findings and has had a good influence on clinical training in geriatrics. NIA continues to receive TNH applications and will continue to fund new projects which receive sufficiently good priority scores in peer review to allow funding from NIA's research grants budget. NIA will continue to require that all proposed TNH projects include nursing schools (or departments of nursing at institutions without a school of nursing). In addition, the present TNHs are continuing to initiate new pilot studies for subsequent full-scale research projects. Many of these pilot studies are developed and staffed by nursing school faculty. NIA is encouraging TNHs to submit proposals for funding of new supplementary projects based on these pilot data.

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DIVISION OF RESEARCH RESOURCES

STATEMENT OF DR. BETTY H. PICKETT, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. JAMES F. O'DONNELL, DEPUTY DIRECTOR, DIVISION OF RESEARCH RESOURCES

WILLIAM R. BELDON, ACTING DIRECTOR, DIVISION OF HEALTH BUDGET ANALYSIS, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. Next we will hear from Dr. Betty Pickett, Director, Division of Research Resources. Dr. Pickett has said that the excellence of today's science and tomorrow's discoveries are dependent upon investigators having access to sophisticated instrumentation and well-equipped laboratories. This Division has responsibility for providing the sophisticated equipment and technical expertise needed by biomedical researchers.

The fiscal year 1986 budget request decreases support for biotechnology by $16 million, and for clinical research by $10 million. So I would like to hear Dr. Pickett present this budget as it relates to her particular views from the value of equipment and instrumentation in the biomedical laboratories.

Dr. PICKETT. Thank you, Senator Weicker.

[The statement follows:]

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STATEMENT OF DR. BETTY H. PICKETT

I am pleased to present the FY 1986 budget request for the Division of Research Resources.

The Division provides for the development, support, and administration of research resources and operates five distinct programs. The Clinical Research Program supports 76 General Clinical Research Centers (GCRCs). These specialized centers provide environments for investigations into the prevention, diagnosis, and treatment of human disease. It is in these centers that laboratory findings can be evaluated for their ability to improve human health. The spectrum of research conducted in the GCRCs includes all the fields of clinical research supported by the NIH research Institutes such as immunology, cancer, nutrition, and diabetes. Examples of recent scientific accomplishments include:

--developing a treatment for a painful and disabling side effect of kidney dialysis called Vitamin-D-resistant osteodystrophy which is characterized by bone pain, muscle weakness, and pathologic fractures;

--a new approach to surgery for inflammatory diseases of the large intestine (such as ulcerative colitis) which prevents post-surgical incontinence of feces;

--development of a method of spinal infusion treatment using thyrotropin-releasing hormone to produce improvements in muscular strength in patients with amyotrophic lateral sclerosis;

--the prevention of calcium-containing kidney stones by administration of a drug that reduces crystallization of the salts that form the stones.

In FY 1986, the Division will continue support for the 76 GCRCs.

The resource centers of the Biomedical Research Technology (BRT) Program provide biomedical scientists access to the latest technological applications of the physical sciences, mathematics, and engineering. The Program provides awards that enable regional and national sharing of resources and resource technologies, provide advanced instrumentation, support research to further develop such instruments for biomedical research, and disseminate information on the application of these research technologies. The BRT Centers comprise one aspect of DRR's efforts to meet the needs of biomedical research for advanced laboratory instruments.

Since our last report to this Subcommittee, the BRT Program has initiated support for regional centers for the development and application of *in vivo* nuclear magnetic resonance spectroscopy and for new imaging technologies. Examples of the Program's accomplishments in other areas are:

--Support for the design and fabrication of a special-purpose digital computing system that will provide computing power comparable to that of a supercomputer for calculating protein configurations and interactions of proteins with other small or large molecules.

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--Further development of the computer-based expert systems for medical consultation. ONCOCIN, now supported by BRT and other NIH components, assists physicians with the management of outpatients enrolled in experimental cancer chemotherapy protocols for the treatment of lymphomas.

DRR's Laboratory Animal Sciences and Primate Research Program now comprises three elements: Regional Primate Research Centers, Laboratory Animal Sciences, and Biological Models and Materials Development. The seven regional Primate Research Centers provide specialized resources and research environments for the broad range of biomedical investigations which require the non-human primate as the research subject.

Work in the Centers includes:

--continued research on simian acquired immunodeficiency syndrome as a model for basic studies relevant to human AIDS;

--investigations which have provided the basis for a collaborative clinical trial of hydroxyurea in sickle cell anemia patients;

--research demonstrating the relationship between higher amounts of insulin in the cerebrospinal fluid and reduced appetite which helps individuals to lose weight and not gain it back;

--studies in animals of the factors which delay the maturation of lungs in the fetus and thereby potentially increase the occurrence and/or severity of respiratory distress syndrome in human neonates.

The Laboratory Animal Sciences Program assists institutions in developing and improving animal resources for biomedical research and research training awards. These include: projects which use vertebrates to model human diseases; diagnostic laboratories that conduct surveillance activities and investigations of naturally occurring disease; training in laboratory animal medicine that prepares individuals to provide professional care of the many species needed in research, to manage central animal resources, and to assist researchers in design of studies using animals; and institutional animal resource improvement projects to help research institutions upgrade animal facilities and develop centralized programs of animal care. The 1985 appropriation provided $5 million for improvement projects; approximately ten awards will be made, and each award will require one-for-one matching support from the institution.

The Biological Models and Materials Development component, organized recently, deals with researchers' needs for *in vitro* cell systems, non-vertebrate organisms, mathematical models, and DNA fragments which are used to locate genes on chromosomes. The Division's activities in this area were initiated in response to requests from the research community for support of a range of biological materials, and biological and nonbiological model systems. The Division developed a data system to document the current usage of various model systems in NIH-supported research projects. In addition, it has carried out an evaluation of the importance and relevance of model systems in biomedical research through a contract

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with the National Academy of Sciences. The Academy study has examined the use of model systems in a wide range of research topics such as cellular immunology, development, learning, biological regulation, and diseases and aging.

The Biomedical Research Support Program consists of three subactivities: the Biomedical Research Support Grant Program; the Shared Instrumentation Grant Program; and the Minority High School Student Summer Research Apprentice Program.

The BRSG is unique in that the grantee institutions themselves allot the funds, according to their own perception of scientific need and opportunity. BRSG funds are most commonly used for small pilot research projects and interim funding, as well as to provide initial support for new investigators, to develop and support central research facilities, and to resolve unanticipated technical problems in ongoing projects.

Through the Shared Instrumentation Grant Program, DRR helps institutions to acquire sophisticated research instruments with awards ranging between $100,000 and $300,000. These instruments are shared by groups of funded investigators. A total of 229 awards was made in 1982, 1983, and 1984. An estimated 171 will be made in 1985. The six instrument types most frequently requested have been electron microscopes, cell sorters, nuclear magnetic resonance spectrometers, mass spectrometers, macromolecular sequencers, and image analysis/computer graphics systems. This Program, the second component of our instrumentation activities, complements the advanced instrumentation resources provided by the Biomedical Research Technology Program discussed earlier.

The purpose of the Minority High School Student Summer Research Apprentice Program is to stimulate interest among minority high school students in careers in science. Minority students are given opportunity to work during the summer in a research laboratory. A total of 2,918 students was supported from 1980 to 1984; an estimated 999 will be supported in both 1985 and 1986, 50% more than in 1984. A study of a sample of 227 students at 18 institutions indicates that 81% have either entered college or plan to do so.

The Minority Biomedical Research Support Program was established in 1972 to provide increased opportunity for the participation of minority scientists in biomedical research. These MBRS grants support research projects that fall in scientific areas of interest to the Public Health Service. In 1984, NIH and ADAMHA, supplementing the funds appropriated to DRR, provided $9.9 million to support 260 projects of the MBRS research program. In 1986, we expect that NIH and ADAMHA will provide approximately $11.0 million to supplement funds appropriated to DRR.

In 1984, the MBRS Program supported 1,020 undergraduate students, 388 graduate students, and 736 faculty in 645 research projects at the 81 participating institutions. Ongoing studies of the Program's outcomes indicate that over 500 of the students MBRS supported during the period 1972-1983 later received M.D. or Ph.D. degrees.

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In 1986, as in the past two years, $1 million of the funds requested will be directed to needs for research equipment at MBRS institutions.

In 1985, two new MBRS subactivities, the MBRS Thematic Grant Program and the MBRS Grant Program for Undergraduate Colleges, were initiated. The Thematic Grant will provide another transitional step toward regular NIH grant support in those institutions which have developed significantly during the past 13 years of the MBRS Program. It supports research projects designed around specific research themes or disciplines.

The undergraduate college program enriches the environment at small undergraduate schools through seminars, visits by scientists, and similar efforts, with the aim of increasing student awareness of science as a potential. In addition, faculty members are provided opportunity to participate in biomedical research.

Mr. Chairman, the 1986 budget request for the Division of Research Resources is $263,040,000, a decrease of $42,364,000 from the comparable 1985 level. The 1986 budget was developed in the context of the Administration's freeze policy. To accomplish this without upsetting the stability of the research program required adjustments in the 1985 spending policies, particularly with respect to the number of centers funded. Specifically, in 1985 this Division will fund 171 centers, of which 29 will receive two years of support.

I will be happy to answer any questions.

Biography of Dr. Betty H. Pickett

Date and Place of Birth: February 15, 1926, Providence, Rhode Island

Marital Status: Married to James McPherson Pickett, 1952

Education: 1945 - A.B. (Psychology) Magna Cum Laude, Brown University
1947 - Sc.M. (Psychology) Brown University
1949 - Ph.D. (Psychology) Brown University

Positions Held:

September 1949 March 1958	- Assistant Professor at University of Minnesota and University of Nebraska; Lecturer in Psychology, University of Connecticut; Professional Associate, Bio-Sciences Information Exchange, Smithsonian Institution, Washington, D.C.
March 1958 March 1961	- Executive Secretary, Behavioral Sciences Study Section; Executive Secretary, Experimental Psychology Study Section, Division of Research Grants, NIH.
August 1962 June 1977	- National Institute of Mental Health: Research Consultant to Mental Health Unit, Region #1; Executive Secretary, Research Career Program; Chief, Cognition and Learning Section, Behavioral Sciences Research Branch; Deputy Director, Division of Extramural Research Programs; Director, Division of Special Mental Health Programs; Acting Director, Division of Extramural Research Programs.

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June 1977 - Associate Director for Extramural and Collaborative
January 1979 Research Program, National Institute on Aging

January 1979 - Deputy Director, National Institute of Child Health
July 1981 and Human Development

July 1981 - Acting Director, National Institute of Child Health
July 1982 and Human Development

July 1982 - Deputy Director, National Institute of Child Health
September 1982 and Human Development

October 1982 - Director, Division of Research Resources
Present

Professional Societies: American Psychological Association; Eastern Psychological Association; Psychonomic Society; Association of Women in Science; American Association for the Advancement of Science; Academy of Behavioral Medicine.

Honors, Awards: Phi Beta Kappa, 1945. Sigma Xi, 1945. University Fellowship, Brown University, 1947-48. A.B., Brown University, Maga Cum Laude, high honors in psychology. DHEW Superior Service Award, 1972. DHEW Distinguished Service Award, 1975. FEW Award for Distinguished Service in Support of Equal Opportunities for Women, 1975. Citation from Graduate School, Brown University for scientific and professional achievement, 1978. Harold M. Hildreth Award, 1979, American Psychological Association (for distinguished contribution to psychology in the public service). Senior Executive Bonus Award for outstanding performance, 1981, 1982, 1983 and 1984.

BUDGET REQUEST

Dr. PICKETT. Before I begin may I introduce the Deputy Director of DRR, Dr. James F. O'Donnell who accompanies me.

I am pleased to present the 1986 budget request for the Division of Research Resources. As you mentioned in your introduction, the Division provides for a range of specialized environments and resources for biomedical research through five distinct programs. The General Clinical Research Centers Program, the Biomedical Research Technology Program, the Laboratory Animal Sciences and Primate Research Program, the Biomedical Research Support Program, and the Minority Biomedical Research Support Program. Principal investigators of more than 5,000 grants worth over $700 million supported by the several NIH institutes utilize these centers and facilities.

Let me just highlight the different programs before proceeding to budget questions. The general clinical research centers provide the settings for work like the important clinical research described by my colleagues over the past couple of days. For example, the large trial Dr. Lipsett mentioned on control of diabetes complications has used beds and outpatient facilities in 18 of the 76 general clinical research centers. Much of the liver transplant research has been conducted in two of the

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centers, and the recent islet cells transplants were conducted in clinical research centers. Eight of our centers are pediatric centers, and two focus on the neonatal period. Much of the work underlying the management of tiny premature babies has been carried out at these GCRC's.

My long statement submitted to the committee presents more examples.

Turning to the primate centers, we can cite a variety of studies relevant to both animal health and disease and a number of human problems and diseases; for example, management of sickle cell anemia and fetal lung maturation problems in human infants. Animal diagnostic laboratories supported by the Division of Research Resources study naturally occurring diseases in laboratory animals with the goal of maintaining and producing healthy animals for laboratory research. One of those labs is at Yale University.

The Biomedical Research Technology Program provides high technology instrument centers to help researchers apply advanced instrumentation to problems in health-related research. These centers are both national and regional, and are available to investigators from other institutions.

Among the studies conducted in the centers are nuclear magnetic resonance spectroscopy, advanced computing, and electron microscopy for studies of cellular and biomolecular structure.

The Biomedical Research Support Program provides the formula grant to research intensive institutions. Flexible funds are provided for pilot studies for noncategorical and/or not easily predictable research needs emergencies, interim support for new faculty, central resources, and similar functions.

The shared instrumentation grants provided by the Division of Research Resources assist institutions to upgrade and replace key laboratory equipment needed by groups of PHS-funded investigators. The Minority High School Student Summer Research Apprentice Program is designed to attract promising minority high school students into the science career pipeline. It has been ongoing since 1980. This year, it will support around 1,000 students, up from the 666 students supported in the past, as a result of the additional funding provided by this subcommittee.

The Division of Research Resources' Minority Biomedical Research Support Program has been ongoing since 1972. It continues efforts to increase the participation of minority scientists in biomedical research. Through this program we support faculty research projects, faculty release time to do research, necessary equipment and facilities, and salary for student assistants on the faculty research projects. More than 600 projects are under way today at the 83 participating institutions, and preliminary data from ongoing studies of student career outcomes indicate a significant number of graduate and health professional advanced degrees received by the students who have participated in the program between 1972 and 1983.

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Our request for fiscal year 1986 is $263,040,000. Specifically addressing the question of centers, in 1985 this Division will fund 171 research centers, up from the 166 supported in 1984. Of these, 29 are planned for 2 years of support. Thus, in 1986, funds will be required for 142 centers, but 171 will be active, since 29 of them will have received 2 years of funding in fiscal year 1985, under the administration's budget plans. I will be pleased to answer your questions.

NUMBER OF BIOMEDICAL RESEARCH TECHNOLOGY CENTERS

Senator WEICKER. Your budget request reduces the number of biotech centers from 62 in fiscal year 1985 to 37 in fiscal year 1986.

Dr. PICKETT. Our budget request reduces the number of biomedical research technology centers from 62 in the 1985 appropriation, to 51 in the 1985 current estimate, to 37 in the 1986 request. Fourteen are expected to be multiyear funded in fiscal year 1985. Thus, although only 37 would be funded under the administration's budget policy in 1986, there will be another 14 that are still active because they will have received 2 years of funding in fiscal year 1985. Thus, there would be 51 active centers, of which only 37 would need to be funded in 1986.

INSTRUMENTATION SHORTAGES AND OBSOLESCENCE

Senator WEICKER. Over the past several years, we have heard testimony alerting this committee that a problem of instrument shortages and obsolescence was seriously interfering with research in the Extramural Program. Congress added $20 million to your budget in fiscal year 1982, and that has risen to almost $50 million by fiscal year 1985.

What are you requesting for 1986?

Dr. PICKETT. For 1986, we are requesting the same amount as in 1985; $31.8 million for the Shared Instrumentation Grant Program.

Senator WEICKER. Of course, these instruments aren't going down in price, as I understand it. I gather the costs have escalated substantially in the types of instrumentation we are talking about, at least every news article I read when new equipment comes on line, certainly it is pretty expensive.

Dr. PICKETT. I would guess the 4.6-percent inflation that is reported applies to that sector of the economy as well as others. I do not know if there is a specific instrumentation inflation rate.

Senator WEICKER. John Doyle tells me that the medical rate of inflation has been about 70 percent higher than the general rate of inflation over the years.

Dr. PICKETT. That is reflected in the differential inflation rate that has been applied to our clinical research centers. That has always been pegged slightly higher than the rest of the health research market basket as I have understood it. We are still looking at it as somewhat higher than this 4.6 percent. I think we are dealing with a 6-percent level for the clinical research centers.

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PRIMATE CENTER RENOVATIONS

Senator WEICKER. It has been estimated $13.5 million will be needed over the next 5 years for total renovation of our regional primate centers. What will be spent in fiscal year 1985 to further the goal of improving those facilities and what is requested for 1986?

Dr. PICKETT. $1 million will be spent in 1985 and $1 million is requested in 1986. We have already expended $1 million in 1984, at the start of this renovation process. So we will, by the end of 1986, have $10.5 million remaining of that estimate.

ACCREDITATION OF PRIMATE CENTERS

Senator WEICKER. Are all seven of the primate centers accredited by the American Association of Accreditors of Laboratory Animal Care?

Dr. PICKETT. Six are accredited. One is not accredited as yet. Its problems, as I understand them, are not in the quality of the care of the animals, or of the health programs for the employees, but in certain physical plant problems. I understand in that case the State government is helping out with some really major expenditures to upgrade the physical plant. We look to accreditation within the foreseeable future.

Senator WEICKER. How long has it not been accredited?

Dr. PICKETT. I'm sorry I can't answer that question.

Senator WEICKER. Please supply that for the record. I would certainly expect that such accreditation takes place this calendar year.

[The information follows:]

PRIMATE RESEARCH CENTER ACCREDITATION

Accreditation of animal facilities by the American Association for Accreditation of Laboratory Animal Care [AAALAC] was begun in 1965. Because of insufficient animal holding space, it has been necessary for the Center under discussion to share animal facilities with one of the university's academic departments. University policy does not allow funds that are available for renovation to be used to upgrade facilities not owned by the Center. However, the university is proceeding through the State budget process to purchase an adjacent building for the Center that could be renovated to provide accreditable animal facilities. As an incentive to help this process along, the Center and university have been advised of the availability of primate center improvement funds this year. If the university is successful in purchasing the adjacent building, the Division of Research Resources will continue to work with the Center so that their facilities may soon qualify for AAALAC accreditation.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record. I thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

ANIMAL FACILITY IMPROVEMENT PROGRAM

Question: The use of animals in research is a continuing concern for this Committee and the research community. Last year you initiated a program that was to spend $5 million to bring animal facilities up to modern humane standards. Can you describe how you utilized the $5 million and explain why you are not requesting continued support?

Answer: The Congress made funds available for this program in 1985. These funds were intended to alleviate some of the immediate needs for improvement of animal facilities at some of the Nation's research institutions. No funds have been obligated to date for this program; however, there has been widespread interest in the program announcement which appeared in the December 7, 1984 issuance of the NIH Guide for Grants and Contracts. More than 250 institutions asked for the Request for Application. As of the March 1, 1985 submission date, we have received 93 applications requesting $35.6 million. These applications will receive scientific review in June 1985, with awards being made to 12-18 successful applicants in September 1985. An award will include up to $500,000 from DRR for the alterations and renovations requested and will require one-to-one matching funds provided by the institution. No funds will be awarded for construction.

No funds have been requested for this program in 1986. This position has been developed out of a growing concern for the Federal deficit.

USE OF ANIMALS IN RESEARCH

Question: I understand that both the National Research Council and the National Cancer Institute have surveyed the need for replacement or renovation of animal facilitites. What is the actual need for this support and how much of that need is being met?

Answer: In 1978, the Institute of Laboratory Animal Resources of the National Research Council conducted a survey providing the only available detailed data upon which to base estimates of the scope of the problem and representing a reasonable assessment of present needs. The survey's findings are summarized below.

1. About 16 percent of all nonprofit biomedical research organizations reported a need for replacement of some animal facility space now in use, 38 percent reported a need for remodeling to protect the integrity of space now in use, and 43 percent reported a current need for additional space.

2. The 1978 needs of nonprofit biomedical research organizations for space replacement, remodeling, and additions to their animal facilities would have required $350 million. Another $407 million would have been needed to meet space needs projected from 1978 through 1988. These same organizations reported a need in their animal facilities of $43 million for equipment renovation, replacement or additions.

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The NCI survey in 1979 was directed to extramural cancer research institutions. Total current (1979) construction needs were $221 million; of this $34 million or 15 percent was for animal facilities. The long range (five year) total requirement was $449 million, of which $51 million or 11 percent was for animal facilities.

In fiscal year 1985, the Division of Research Resources will have $5,000,000 available for the improvement of laboratory animal facilities. Awards will include up to $500,000 in matching funds for alterations and renovations. The Division expects to make 12 to 18 awards in September 1985. There are 93 applications currently under review.

BIOMEDICAL RESEARCH TECHNOLOGY PROGRAM

Question: We have been told again and again that biotechnology is at the point of the biological revolution. Your budget request reduces the number of Biomedical Research Technology centers from 62 in FY 1985 to 37 in FY 1986. What is the impact of the FY 1985 OMB budget and the 1986 request on the Biomedical Research Technology program?

Answer: The majority of the Biomedical Research Technology program budget is for the support of resource center grants. The 1985 appropriation contained a significant increase for the centers component over 1984 for real growth and expansion of the BRT centers program. As part of the Administration's multiyear funding policy, this increase would be used primarily for the second year of support for 14 existing centers, thus reducing the number of centers we can support from 62 to 51, and also reducing the level required in 1986 to maintain the same program level of support as in 1985. This action would enable the Division to maintain a relatively stable base of 51 active centers in 1986 with a budget request of $26,975,000 for the BRT program; $16,458,000 below the 1985 current estimate.

IMPORTANCE OF ELECTRON MICROSCOPY AND NMR RESEARCH

Question: You requested grant applications in the area of electron microscopy and nuclear magnetic resonance. Can you tell us why these programs are important and how your budget request impacts on these two areas of biomedical research?

Answer: A number of new techniques for investigation of biologically important structures in cells and tissues have been developed in recent years. One of these, intermediate voltage electron microscopy (IVEM), is now at the stage of development for application in biomedical research. In particular, studies on how the cell establishes and maintains its three-dimensional organization and how it controls its size and shape should be possible using this new instrument. Two regional centers for IVEM research studies by biomedical scientists have been established, and other applications submitted in response to the Biomedical Research Technology program's announcement of interest in this area are under review.

Nuclear magnetic resonance (NMR), particularly when used as a non-invasive monitor of organ and tissue metabolism, is another important new technique developed recently. Several research scientists have demonstrated that it is possible to follow energy

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metabolism in muscle directly, and to diagnose some metabolic malfunctions which involve such metabolic cycles. In addition, studies on the chemistry of other organs and tissues, including the brain, heart, liver and kidneys are being proposed or carried out. The BRT program has funded two resources for the further development and application of these methods in medicine and biology. The applications are a natural extension of previous program interest in biochemical aspects of NMR spectroscopy. Further requests are being reviewed at this time.

The 1986 budget request will enable us to maintain support for all existing electron microscopy and NMR centers, at the same average cost per center as in 1985. No new center awards are expected to be made in 1986.

INSTRUMENT OBSOLESCENCE

Question: Over the past several years we have heard testimony alerting this Committee that a problem of instrument shortages and obsolescence was seriously interfering with research in the extramural program. Congress added $20 million to your budget in FY 1982, and that had risen to almost $50 million by FY 1985. What impact has this increased funding had on the problem of instrument obsolescence and shortage?

Answer: The funds earmarked for the Biomedical Research Support-Shared Instrumentation Grant (BRS-SIG) program have been very helpful in alleviating the problems of acquiring expensive instrumentation. To date, in four years of operation, the BRS-SIG program has received over 700 applications requesting over $150 million in instrumentation. In FY 1982, 1983, 1984 and 1985, 400 awards for a total of $69.3 million were made to medical schools, graduate schools, research organizations and hospitals to meet the backlog of accumulated research instrumentation needs.

Question: How much remains to be done?

Answer: The instrumentation problem has many causes, not the least of which is the pace of technological progress, which quickly renders scientific instrumentation obsolete. Newly developed instrument capabilities continue to open up new research opportunities. The instrumentation problem in the $100,000 to $300,000 range is not only an acute problem today, but will be a continuing problem in the foreseeable future. With the increased use of microprocessors, the development of new technologies, and the demand to update equipment, institutions will always be faced with the need to improve instrumentation, especially that shared by a broad group of users. An indication of the continuing need is the fact that, for FY 1986, DRR has already received over 250 applications for shared instrumentation grants, requesting nearly $60 million.

Question: What are you requesting for FY 1986?

Answer: The President's FY 1986 Budget includes $31.8 million for the BRS-SIG program.

Question: How much more is needed to keep the Programs on track?

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Answer: Effective technological support requires stable research support not only to maintain and sustain the current equipment inventory but also to ensure that new modalities which are continually evolving or being improved are accessible to keep research investigators on the frontiers of science. The amount requested in the President's Budget, $31.8 million, should be sufficient to keep the program on a reasonable track.

PRIMATE CENTER RENOVATIONS

Question: It has been estimated that $13.5 million will be needed over the next five years for total renovation of our regional primate centers. What will be spent in Fiscal Year 1985 to further the goal of improving these facilities?

Answer: Within the 1985 appropriation, as well as the 1985 current estimate, there are $1.0 million included to continue to address the repair and renovation needs at the primate research centers. We expect to use the $1.0 million in 1985 to begin the repair of roofs at several centers, improved sewage disposal systems, renovation of ventilation and sanitation equipment, additional caging and cage washing equipment, and the replacement of obsolete research equipment items.

Question: What is requested for FY 1986?

Answer: One million dollars is included in the 1986 request to continue to address the repair and renovation needs of the primate centers.

GENERAL CLINICAL RESEARCH CENTERS

Question: Please describe why a General Clinical Research Center is important.

Answer: A General Clinical Research Center (GCRC) is a resource located in a major teaching hospital where controlled studies on patients can be conducted in an optimal manner. A GCRC contains dedicated beds, an outpatient unit, specialized research equipment and a staff of research nurses and dieticians. Physicians with funding from various components of NIH and other sources, admit patients to the center for particular studies which require the special environment of a GCRC for conducting a protocol and collecting the data. Many of these studies would be difficult or impossible to carry out within the general hospital setting since the critical equipment and personnel would not be centralized. Conducting clinical investigation in a decentralized manner would also be less cost efficient due to duplication of resources. Additionally, a GCRC provides a site for collaborative research as well as opportunities for clinical research training of young physicians, nurses and dieticians.

Question: The FY 1985 appropriation provided funds for 77 of these centers. Why are you requesting funding for only 72 in FY 1986?

Answer: The 1985 appropriation bill provided an increase of $6,380,000 over the 1985 President's Budget in the Clinical Research Program for 2 new General Clinical Research Centers, restoration of

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the direct cost reductions which had been proposed in the 1985 President's Budget, and additional funds for technology improvement in the centers. As part of the Administration's multiyear funding policy, this increase would instead be used primarily to provide the second year of support to 4 of the existing GCRCs in 1985. This action would reduce the dollar level required in 1986 to maintain the same program level of support as in 1985. Although the Division will keep 76 GCRCs active in 1986, funding will be required for only 72 centers in 1986, since 4 centers will have been funded for 2 years from funds made available in 1985.

Question: What is the impact on ongoing research at institutions losing the Centers?

Answer: Seventy-six GCRC's will be active in FY 1985 and FY 1986; 72 will receive FY 1986 awards, and 4 are to receive multiyear awards in FY 1985. Therefore, no currently existing center will be terminated because of lack of funds in FY 1986.

Question: Do you have any applications under review that you feel should be funded?

Answer: Currently, there are seven applications for new GCRCs under review. We anticipate that several of these applications will be of very high scientific merit. Under the FY 1986 budget we will not fund any of these applications, unless one or more of them would replace centers of lower scientific merit which will be competing for continuation support in FY 1986.

1986 FUNDING FOR MBRS PROGRAM

Question: The purpose of the Minority Biomedical Research Support (MBRS) Program is to provide expanded opportunities for careers in biomedical research. The DRR 1985 budget included $24,951,000 to support 83 minority biomedical research projects. Will there be increases or decreases in the support of MBRS projects for Fiscal Year 1986?

Answer: The 1986 budget request for DRR includes $24,951,000, the same amount as in 1985. This level will support 4 fewer awards than in 1985; however, the 79 remaining awards will be fully funded and not be subject to any downward negotiations. Co-funding by other NIH institutes in 1986 of MBRS projects is estimated to be approximately $10,080,000, an increase of $162,000 or 1.6% over the 1985 estimate of $9,918,000. Therefore, total support for MBRS projects in 1986 is estimated to be $35,951,000, an increase of $162,000 or 0.5% over the 1985 estimate of $35,789,000.

PREVENTION RESEARCH

Question: What types of preventive research are being done by your institute?

Answer: Scientists utilizing DRR resources are working in all areas of prevention. Topics of special concentration include:

o Pregnancy and infant care among adolescents, low-income persons, and those at risk of genetic diseases; genetic counseling

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and followup of high risk neonates; developmental disability screening of preschool and elementary school children.

o Research to improve the nutritional status of mothers, infants and pregnant teenagers; effects of diet, including dietary ratios of fat, carbohydrates and proteins, on health status.

o Risk factors related to coronary heart disease, such as hyperlipoproteinemia, cholesterol, hypertension, salt consumption, and stress, studied in conjunction with nutritional habits.

While all of DRR's programs support research on disease prevention, by far the largest concentration of projects in this area is in the General Clinical Research Centers.

Question: What percent of your budget is directed to preventive research?

Answer: In 1984, DRR directed $30.7 million or 12.6 percent of the Division's total budget, to projects related to preventive research. It is estimated that in 1985 and 1986 DRR will direct approximately 12% of its budget to projects related to preventive research.

Question: How are the results of this research being translated into useful public information?

Answer: As a member of the trans-NIH Prevention Committee, the Division contributes to the information dissemination efforts of that committee, including the publication of scientific program highlights through the publication "Research in Prevention". In addition, the Division communicates results of prevention research to both the medical and lay communities through its "Research Resources Reporter", a widely distributed periodical printed monthly by the Research Resources Information Center.

HISTORY OF LEMSIP

Question: Over the past several years, the Committee has been receiving a great deal of mail concerning the funding of an active primate center in N.Y. State called LEMSIP. We have been told by respected researchers from schools in the Northeast that this primate center is an important resource and that "it would be impossible for scientists to do important work..." on primates without it. Please review NIH's entire grant review and funding denial history with LEMSIP and inform the Committee what LEMSIP must do to qualify for support.

Answer: We are working with LEMSIP to assist them in preparing an application for research grant support. Once LEMSIP has submitted an application, it must pass peer review by an NIH scientific review group and a national advisory council. The LEMSIP has qualified for NIH support in the past. This support is listed below.

According to our records, the following DRR grants/contracts have been awarded to LEMSIP:

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DRR Grant/Contract	Period	Amount Awarded
Grant RR00316	05/01/66-04/30/74	$ 731,395
Grant RR00839	06/01/74-05/30/75	19,700
Grant RR01082	07/01/77-12/31/80	620,061
Contract NO1 RR4-2184	06/01/74-06/29/76	441,905
Contract NO1 RR6-2132	06/30/76-05/31/79	1,193,222
Total		$3,006,283

In addition, the Blood Division, NHLBI, supported contract NO1-HB4-2971, "Acquisition, Breeding and Maintenance of Chimpanzees for Hepatitis Research at LEMSIP". The period of performance for this contract was June 30, 1974 through June 29, 1979. The total amount awarded for the contract through its expiration date was $1,709,784.

Other grant proposals which have been submitted by LEMSIP to DRR are as follows:

1. RR00907-01, "A Primate Center for the New York Metropolitan Area". This application for the establishment of a Regional Primate Research Center was submitted on October 1, 1973. The application was recommended for disapproval by the National Advisory Research Resources Council (NARRC) on March 15, 1974, primarily because of the lack of a core research program; thus, LEMSIP did not adequately meet the established criteria for a Primate Research Center.

2. RR01012-01, "New York Metropolitan Primate Center". This application for the establishment of a Regional Primate Research Center was submitted on February 1, 1975. The application also was recommended for disapproval by the NARRC on June 30, 1975, because of the lack of an adequate core research program.

3. RR01082-04, "Blood Groups in Primates". This competing renewal application was recommended for approval by the NARRC at its meeting on October 15-17, 1980. The application was administratively withdrawn because its priority score was below the funding cutoff.

4. RR01082-04A1. A resubmission of the same competing renewal application, "Blood Groups in Primates", was recommended for approval by the Initial Review Group in October 1982. The NARRC recommended disapproval of this application at its meeting on February 3-4, 1983. This disapproval was based on the fact that the reviewers noted that only the service function of the proposal had scientific merit; the research proposed was not of high quality. Therefore, on policy grounds, the Council stated that a research resource grant was not the appropriate support mechanism and suggested that LEMSIP consider contract support for this activity.

POLICY FOR THE CARE AND USE OF LABORATORY ANIMALS

Question: The Public Health Service, working through NIH's Office for Protection from Research Risks, has put forth proposals to change its policy with respect to the care and use of animals at federally funded institutions and laboratories. Many of these facilities are subject to scrutiny by the U.S. Department of Agriculture through enforcement of the provisions of the Animal Welfare Act. However, the Administration's budget (Department of

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Agriculture) for fiscal year 1986 contains no funding for continued animal welfare enforcement. In fact, language from a budget briefing document stated, "Animal and Plant Health Inspection Service will discontinue all inspections of licensed dealers, research facilities, exhibitors and carriers. There will be no Federal investigations of complaints or alleged violations and cooperative efforts with other government agencies will cease." If the announced withdrawal of APHIS inspections to enforce the Animal Welfare Act is sustained by the Congress, will there be any impact on what NIH is trying to establish with regard to its new proposals aimed at improvements in animal care at awarded institutions?

Answer: Among other requirements, the Public Health Service Policy requires grantee institutions to comply with the Animal Welfare Act. NIH has no authority to enforce the Animal Welfare Act. Consequently, enforcement and monitoring of the Animal Welfare Act are very important to the NIH program to assure that all grantee institutions using research animals maintain high environmental and care standards for these animals. PHS policy requires that NIH awardees abide by the Animal Welfare Act. Without APHIS inspection and reports, their assurance could not be verified.

Question: Will the Department of Agriculture's plan to get away from animal welfare enforcement reduce or enhance NIH's credibility with respect to insuring that animals used for research purposes, and paid for with taxpayers' dollars, are being treated as humanely as possible?

Answer: NIH has a memorandum of agreement with APHIS that we will exchange information about any serious violation of the Animal Welfare Act. NIH administrators frequently utilize APHIS reports in their review of institutional animal care programs. Without APHIS, NIH's ability to maintain awareness of the welfare of animals used in research supported by Federal funds would be impaired.

ANIMAL USE IN BIOMEDICAL RESEARCH

Question: One of the roles of the Division of Research Resources in biomedical research is to find or identify animal disease models that closely mirror human illness. Animal welfare and animal rights activists continue to persist in their demands that alternatives or adjuncts be used to replace many of the animal species subject to experimentation. While the immediate replacement of laboratory animals by alternative measures can be debated, how much of DRR's or NIH's budget goes towards discovering new live animal models versus developing validated and useful replacements?

Answer: Though the concepts of alternatives, adjuncts and replacements are clearly useful in discussion of the selection of systems for test methods development, these terms have little applicability to discussions of selection of model systems in biomedical research.

An explanation of this matter of selection of model systems and models development in biological research is presented in the report of the National Academy of Sciences Committee that conducted a recent evaluation of "Models in Biomedical Research." The DRR and the NIH Institutes presently are determining an appropriate response to the NAS recommendations on models development. Any component of

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NIH that supports a program which develops specific animal models for research does so because an animal model is needed to answer important questions relevant to that Institute's health mission. In other words, it is the question asked that determines the nature of the model systems available for use. It is part of the discipline of science to select the most appropriate model system for the biological phenomena to be studied.

Some NIH programs indeed seek simple models to study existing endpoints in the area of toxicology, carcinogenesis and mutagenesis assessment, but they do not specifically seek replacement of specific animal models with nonanimal systems. Many nonanimal model systems are developed throughout the programs of the NIH and these are used routinely in investigations of questions where their use is appropriate.

In FY 1983, about 43% of all research projects supported used nonhuman mammals as models; and about 25% used other systems as models, such as invertebrates, nonmammalian vertebrates, in vitro systems, bacteria, viruses, and mathematical or computer simulations. Development of new methodology or new models is part of each of these areas of research.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: NIH is experimenting with delegating greater authority to certain grant-receiving institutions to determine the acceptability of reprogramming requests. If successful, fewer of these requests would require NIH action. A principal component of the administrative costs in the extramural program is the review of competing grant applications and contract proposals. DRR is studying the average length of the competing segment (i.e., the average interval between recompetitions) of its grants. For each year added to the interval, the costs of competing review can be delayed another year, and replaced with the less expensive process of monitoring ongoing grants. Similar decisions to award contracts for longer, rather than shorter project periods, can help to reduce administrative costs.

The NIH Director's Advisory Committee has reviewed other concepts for reducing the amount of administration and their costs. As an example, in one such concept, investigators' requests for funding would be evaluated in light of their prior productivity, rather than on the merits of a particular grant proposal.

Technology will help us. NIH is now studying computer-based printing of summary statements and other documents resulting from the review process. Replacing paper with electronic filing, transmittals, etc., may produce savings. Similarly, using commercial telecommunications networks to transmit and receive grant applications and contract proposals, award notices, and progress reports would not only speed their movement, but also reduce costs associated with their movement.

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Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: The Division of Research Resources continues to seek ways to reduce administrative costs and to improve administrative efficiency. For example, we participate in the NIH suggestion program. We are currently participating with the NIH Productivity Committee to identify activities which can be done by contractors. We are also participating in studies of staffing assignments within the Bureaus, Institutes, and Divisions; these studies will show us more about gaining additional efficiencies. When appropriate, we conduct evaluation studies of our program operations. Those studies frequently review administrative efficiency as well as program effectiveness.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: We plan to reduce our personnel requirements by five FTEs (5 percent) between 1984 and 1986. A major contribution to that reduction will be the use of new technologies in the Division. Significant changes in procedure include: (1) increased use of computers for inter-Institute communications; (2) increased direct access of the information in the NIH grants information systems (IMPAC and CRISP) instead of written requests to other NIH personnel for that information; (3) the additional capacity of microfiche for storage of important grants records to replace the retention of paper reducing the required storage space and contributing to more effective file retrieval procedures; (4) the use of an optical character reader to move printed documents easily between otherwise incompatible word processors. Microfiche is also being used in other parts of NIH for transmittal of documents to scientific reviewers who have been provided readers by NIH. The costs are alleged to be lower than the costs of producing and mailing paper.

Personal computers are being used to plan, organize, and schedule review activities. In addition, various data bases are maintained to monitor the status of applications through the review process. Thus, some functions formerly performed by staff are now carried out by automated equipment. In particular, all review reports are prepared using word processors, and an optical character reader has been interfaced to a word processor to eliminate the need to retype some materials already typed outside the Review Office.

Another sort of procedural change is the method of organization. In the past two years, DRR has centralized both its scientific review and program planning and evaluation activities in two new offices. Both these changes have brought new levels of effectiveness and efficiency. Ongoing changes in our Grants Management Office will accomplish similar ends.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

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Answer: The review of competing proposals and applications continues to be one of the keystones in the NIH process of selecting and awarding only the most meritorious grants and contracts. Even though overall administrative costs are reduced, the review process has been protected. For example, although less funding is available for travel to review applications on site, DRR's policy is that travel for this review is the top priority; consequently, all needed site visits are made.

In the past, the major mechanism available for review appeals was through submission of a revised grant application. The NIH Guide for Grants and Contracts, Volume 14, Number 4, dated March 29, 1985, contains guidelines for the new NIH Peer Review Appeals System. This process is intended to resolve those concerns which arise from perceived shortcomings or errors in the substance or procedure of peer review--i.e., from receipt and assignment of an application through its review by a National Advisory Board/Council. This system should allow clarification and/or resolution of many issues during the review cycle, thus reducing revised applications submitted for appeal purposes. In fact, when an investigator and his/her institution appeal jointly, the application in question will be withdrawn from the regular review process until the appeal is resolved.

Questions Submitted by Senator William Proxmire

ANIMAL FACILITIES IMPROVEMENT PROGRAM

Question: Dr. Pickett, I note that your $5 million animal facilities improvement program will be terminated in fiscal year 1986. Can you tell us why?

Answer: No funds have been requested for the animal facilities improvement program in 1986. This position has been developed out of a growing concern for controlling the Federal deficit.

PROPHET II

Question: Dr. Pickett, on page 237 of your justifications you indicated that a contract for a PROPHET II second generation computer resource is expected to be awarded during fiscal year 1985. Can you tell us what the total system will cost and how it will be used?

Answer: The cost for the PROPHET II contract for a period of 54 months is $8,147,318. This budget includes software development, developmental and operational hardware, and 24 months of user support.

The present system, PROPHET I, uses a centralized, time-sharing configuration. Telecommunications costs can be high and many simultaneous users can cause the system to respond slowly. The PROPHET II configuration will have distributed "intelligence." Scientists will work at personal workstations, which they may already own, using software and data "downloaded" only occasionally from a central facility. Telecommunications costs will be much reduced, and adding users will require primarily adding inexpensive local work-stations. Therefore, the number of scientists taking advantage of the new PROPHET system for their research data management, data

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analysis and hypothesis formulation, and for collaborative research projects and scientific communication, can increase almost without limit.

In the past PROPHET has supported many research collaborations such as joint research between pharmacologists in Oregon who collaborated with X-ray crystallographers in Buffalo, New York, and both have collaborated, using PROPHET, with clinicians at a V.A. facility in Minnesota. We anticipate that collaborative projects such as these can be multiplied many times with the new capabilities we are developing. We foresee, for example, that scientists gathering cancer data in Puerto Rico, can interact intensively, and efficiently, via PROPHET with oncologists in the continental U.S.

PROPHET I is, at present, in use at 40 locations. It is technology limited and can support no more than 1,000 scientists. We are taking immediate steps to increase the capabilities of PROPHET I, as well as developing the new system. We anticipate that the long term potential of PROPHET II will be much greater than that of PROPHET I.

NATIONAL ACADEMY OF SCIENCES STUDY

Question: Dr. Pickett, I was interested to learn about the Division's new program to develop new research methods using lower organisms and nonliving models. Your statement touched briefly on this new effort as well as the evaluation recently completed by the National Academy of Sciences. I understand the Academy's study was completed days ago. Have you had a chance to review this document yet or is it still in the Academy's pipeline?

Answer: We received the final report of the Committee on Models in Biomedical Research on March 25, 1985. "Models for Biomedical Research: A New Perspective", is an excellent report that provides recommendations the DRR's new Biological Models and Materials Resources Section is using as a basis for program development. We have found this document clear and useful in dealing with the issue of how model systems are selected and used as scientists seek knowledge of human health and disease.

NONANIMAL RESEARCH MODELS

Question: Assuming the study indicates that additional research in biomedical research model development is possible, will DRR solicit applications in this area?

Answer: The Division is exploring means of implementing the recommendations of the Academy report, "Models for Biomedical Research: A New Perspective". One possible implementation activity would be the issuance of program announcements and requests for applications. Several workshops planned by the Division's new Biological Models and Materials Resources Section seek specific advice on the Academy's recommendations. The report has been circulated to the Institute Directors at NIH for their reaction and recommendations for possible implementation. The processes outlined above have only just begun since the report's receipt on March 25, 1985.

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NUMBERS OF BIOMEDICAL RESEARCH TECHNOLOGY CENTERS

Question: Dr. Pickett, last year's budget material indicated you planned to support 52 biomedical research technology grants in 1984. In actuality you funded only 47 grants. Can you tell us what caused the shortfall?

Answer: Based on average cost projections, we estimated that 52 Biomedical Research Technology (BRT) Centers could be awarded with the funds available in the 1984 appropriation. However, at the end of 1984, the BRT program had actually funded only 47 centers, 5 fewer than had been expected because the average cost per center was approximately 28 percent higher than in 1983. This was based on the need of several centers for large, expensive pieces of equipment in order to carry out the research proposed. Furthermore, in 1984 the BRT program announced new initiatives for high field nuclear magnetic resonance spectroscopy resources and for intermediate voltage electron microscopy resources. The high cost of the new awards in these areas also contributed to the shortfall in the number of BRT Centers funded in 1984.

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JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES

STATEMENT OF DR. CRAIG K. WALLACE, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. CORALIE FARLEE, ASSISTANT DIRECTOR FOR PLANNING AND EVALUATION, JOHN E. FOGARTY INTERNATIONAL CENTER

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

BUDGET REQUEST

Senator WEICKER. Next we will hear from Dr. Craig Wallace, Director of the John E. Fogarty International Center, which administers exchanges of scientists and scientific information on an international basis. It also has the responsibility to channel a portion of this appropriation to the Gorgas Memorial Institute for the Gorgas Memorial Laboratory, which conducts research in tropical diseases.

Dr. Wallace is here to present the Institute's fiscal year 1986 budget request of $11 million, of which $2 million will be for the Gorgas Memorial Laboratory.

Dr. WALLACE. Thank you, Mr. Chairman. I would like to introduce Dr. Farlee, the Assistant Director for Planning and Evaluation, Fogarty International Center.

At this juncture, I would like to interject a historical digression. American biomedical research really didn't come into its own until the 20th century. There were no biomedical scientists of stature and no significant research contributions. This is true despite a number of devastating epidemics in the United States, most notably three very severe cholera epidemics. Therefore, the Marine Hospital Service dispatched a Dr. Joseph Kinyoun to Europe to try to find ways in which we could help combat this situation. He returned to the United States in 1887 to set up a one-man hygienic laboratory on Staten Island where he could best address the numerous medical problems we were facing with America's large number of immigrants. It was from this humble beginning that the NIH rose to its present eminence.

I submit, since this time international relationships have continued and expanded, and we at the Fogarty International Center have tried to encourage and maintain the international linkages on many levels. For individual scientist-to-scientist linkages, we have the International Re-

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search Fellowship Program which allows young researchers from abroad to study in institutions in the United States.

Conversely, we have the Senior International Fellowship Program which allows mid-career American investigators to go abroad and work on problems of mutual concern and interest.

We also maintain for the National Institutes of Health the Visiting Program which allows foreign scientists at all levels to come and work on research problems on the campus of the NIH. And finally, we have the Scholars-in-Residence Program which brings eminent scientists to work on the campus transcending all barriers and institutes to address biomedical problems of concern to America and worldwide concern.

To follow the analogy of international linkage further, we encourage institution-to-institution linkages. The National Institutes of Health participate in some 55 bilateral agreements with 32 countries. Over one-half of these are government-to-government science and technology agreements. Likewise, as you mentioned earlier, we are happy to present to you the budget for the Gorgas Memorial Laboratory which has had a 58-year, institution-to-institution linkage with the United States.

The achievements of this laboratory, of course, are well known to your committee.

Then finally we have the capability to bridge biomedical research problems by viewing them from an international perspective. In this area, we organize conferences, workshops, committees where we can address various problems of American and international concern. For example, we have looked at some 15 disease candidates for potential eradication and, indeed, have identified three diseases—measles, paralytic polio, yaws, and other treponematoses—that are potentially eradicable in the foreseeable future, and we are bringing resources together to address these problems.

We are also considering the issue of preventable disabilities. One out of every ten people worldwide is said to be disabled. There are a diversity of other subjects we are considering—asthma, use of antibiotics worldwide, oncogenes, metastatic disease. I submit there has been a leit motif of international linkage throughout NIH's 100 year history, and I further submit that the resource investment has been minimal but the achievements have been significant.

I will be happy to answer any questions.

PREPARED STATEMENT

Senator WEICKER. Thank you. We will include your statement in its entirety at this point in the record.

[The statement follows:]

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Statement of Dr. Craig K. Wallace

Maintenance of U.S. leadership in biomedical science remains important despite budgetary constraints. It is particularly critical to recognize the increasing challenge to our country's prominent position and the nature of the Federal Government's role in advancing science and technology. These thoughts were expressed most recently by the President's Science Adviser in an interview for the science policy bulletin Science and Government Report.

The United States and the NIH in particular are at the forefront of global progress in the biomedical sciences; it is the responsibility of the Fogarty International Center (FIC) to facilitate and coordinate that role at the international level. As Director of the Center, I am pleased to report that, in addition to being responsive to a change in worldwide conditions, we anticipate future needs by stimulating and enhancing biomedical cooperation within the international community.

In fulfillment of our specific mission, the FIC continues to promote the interaction of U.S. biomedical scientists with scientists throughout the world and to provide coordination for the NIH and its research institutes in the conduct of international activities. I will elaborate on our accomplishments in these areas.

Under our program to provide collaborative research opportunities in U.S. laboratories for foreign scientists in the early stages of their careers, we find that not only do most of these former research fellows remain active as research scientists when they return to their home countries, but they also publish in journals of international importance, making their research findings readily accessible to U.S. scientists. After their fellowship year, we find a pattern of continuing relationship and collaboration with U.S. scientists and note that former fellows become recognized experts in their areas of science, often as advisors to national and international science policy organizations and as participants on advisory boards of journals. Our linkages with other countries in our hemisphere were further enhanced in 1984 by the establishment of two additional Nominating Committees, which recommend applicants for NIH peer review: one in Costa Rica and a regional one to include other Latin American countries--bringing the total to 52 throughout the world. Contacts among former fellows, national leaders in science who nominate them for International Research Fellowships, and U.S. hosts and other colleagues help our country benefit from scientific advances being made elsewhere and cooperatively contribute to new knowledge of disease processes.

U.S. participation in our fellowship programs enhances our domestic academic institutions and contributes significantly to science, internationally. To supplement FIC's resources for U.S. scientists, we have been successful in arranging for opportunities for foreign fellowships from nine countries, most recently Finland, Israel, Norway, and Taiwan, while discussions continue with both Italy and Japan.

The FIC is also the focal point at the NIH for the development and oversight of NIH participation in formal and informal cooperative agreements and programs with other countries. At present, 55 agreements with 32 countries form much of the framework for collaborative

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international research activities of all the NIH components. Twenty-five of these agreements have been made at the government-to-government level for broad cooperation in science and technology.

In addition, the NIH is engaged in collaborative research with some 50 countries in the absence of formal agreements. I should emphasize that the international biomedical research activities supported by the NIH benefit U.S. public health by expanding the base of knowledge required for solution of domestic health problems and by stimulating other countries to undertake research of potential value to our own public health pursuits. In fact, many of the research projects being supported take advantage of unique opportunities in terms of unusual disease prevalence, population mobility, genetic determinants, and environmental risk factors.

A few examples will serve to illustrate the value of ongoing work. As you know, AIDS represents a public health emergency for U.S. citizens at home and abroad in that, once contracted, the ultimate mortality rate is virtually 100 percent. Clinical and field epidemiological studies are being conducted in Zaire, where the disease is not seen predominantly in homosexuals and drug abusers and where the distribution of disease in males and females is markedly different from that in the United States. Through such collaborative efforts with scientists in Zaire, we hope to gain insight into alternate routes of infection.

As a result of contacts fostered under the health protocol with China, major epidemiological investigations are evaluating the relationship between dietary components and cancer. China's recent completion of a comprehensive national cancer mortality survey, coupled with the population's stable food intake and low migration patterns, provides a unique opportunity to gain information on potential causes of cancer that would be far more difficult to discern if studied in U.S. populations alone.

Hypertension is a problem in both industrialized and developing countries. Through cooperative arrangements with several countries, we are expanding our knowledge of factors that may be responsible for the different rates of hypertension in these countries. For example, joint studies with Japan and the Soviet Union are focusing on hypertension in children and the potential influence of variables such as nutrition, stress, and genetic predisposition. These studies are expected to contribute to the development of new national and international approaches to the prevention and treatment of cardiovascular disease.

Advanced International Studies at the Fogarty International Center constitute a fundamental way in which the FIC helps the NIH maintain worldwide leadership in biomedical research. For example, under the Scholars-in-Residence component, a scholar from Israel, whose expertise is in immunology and molecular biology, organized in conjunction with a U.S. scholar and an NIH scientist an international conference on oncogenes--genes that have been implicated in causing some cancers, but that otherwise have a normal function in cell growth and differentiation. Knowledge of normal cells is also enhanced by the study of oncogenes, and tumors can now be classified according to the type of oncogenes involved. Understanding of pathways by which oncogenes function may also help devise new methods of therapy. Useful therapeutic applications are also likely as a result of this

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knowledge. This conference was one of the largest and most exciting meetings in the history of the NIH, with 1,300 attendees from many countries.

In another project, global disabilities are being studied by a Fogarty Scholar-in-Residence from England. Initial interest in "Deafness in Developing Countries and Approaches to Prevention" is now leading to the development of a joint plan with the United Nations Program on Prevention of Disability.

The International Studies area of the Advanced Studies Program identifies health issues of international importance to the future directions of biomedical research and develops strategies to address these issues. In our series on the control or eradication of infectious diseases, we have held and are planning significant projects culminating in international conferences. During 1984, we studied the feasibility of improved control and potential eradication of yaws and other endemic treponematoses, a precarious situation in Africa, where high proportions of children are found to have infectious yaws. At the FIC conference, it was determined that the interruption of human transmission of yaws, endemic syphilis, and other venereal diseases prevalent in tropical America is technically possible. Thus, the FIC proposed an initiative to the World Health Organization (WHO) to hold regional workshops to examine the potentials for improved control.

According to a recent FIC-organized conference, rubella vaccines were determined to be safe, to be efficacious, and to provide long-term protection against congenital rubella infection. An urgent need was expressed for the development of international standards for serological testing and interpretation of results. The development of a pool of reference sera and standardized protocols for testing is now being coordinated by the Centers for Disease Control as a result of this FIC effort.

Dr. Albert Sabin, currently a senior scientific expert at the FIC, is following up recommendations from the 1983 International Symposium on Poliomyelitis Control, sponsored by the FIC. In collaboration with other national governments, with private organizations, and with international organizations, Dr. Sabin is working with Rotary International and the WHO's Expanded Program on Immunization to incorporate annual national vaccination programs into routine health services in developing countries where polio is still a major problem.

Development of practical methods for mass use of aerosolized measles vaccine and other approaches to measles vaccination on a mass scale in a short period of time, a direct consequence of the 1982 FIC symposium on measles, is also being coordinated by Dr. Sabin while he is at the FIC.

A number of strategies for enhancing a closer partnership and involvement of the technologically advanced countries with the emerging countries in health research through international collaboration are being pursued by FIC as the WHO Collaborating Center for Research and Training in Biomedicine. One of the initial activities consists of assessment of medical entomology education and training needs for research and control of vector-borne diseases in the Americas. Along with the FIC and the NIAID, representatives of

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the Centers for Disease Control, the Health Resources and Services Administration, the Pan American Health Organization, the World Health Organization, and the Gorgas Memorial Laboratory are planning this assessment. The Gorgas Memorial Laboratory in Panama will be the site of the regional workshop to be held in the fall of 1985.

This is a brief overview of selected research-related activities of the Fogarty International Center. To support these activities, as well as to provide core support for the Gorgas Memorial Laboratory in Panama, we request an appropriation of $11,359,000 for FY 1986. Mr. Chairman, I would be happy to answer any questions.

Biography of Dr. Craig K. Wallace

December 4, 1928. Woodbury, N.J. Married, three children.

Education. A.B. (cum laude), Princeton University, 1950. University of Virginia, School of Law, 1951. M.D., New York Medical College, 1955

Professional History. 1955-1960, Intern, Medical Resident, and Chief Resident, Jefferson Medical College Hospital, Philadelphia, Pa. 1960-1963, Clinical Investigator, Naval Medical Research Unit (NAMRU) No. 2, Taipei, Taiwan. 1964-1969, Assistant Professor of Medicine, The Johns Hopkins University School of Medicine. 1964-1970, Assistant Professor of Pathobiology, The Johns Hopkins University School of Hygiene and Public Health. 1964-1966, Resident Coordinator and Head, Medical Program, The Johns Hopkins University Center for Research and Training (CMRT), Calcutta, India. 1966-1969, Assistant Physician, The Johns Hopkins Hospital. 1967-1972, Associate Director, The Johns Hopkins University CMRT. 1969-1972, Associate Professor of Medicine, The Johns Hopkins University School of Medicine. 1969-1972, Physician, The Johns Hopkins Hospital. 1971-1972, Associate Professor of Pathobiology, The Johns Hopkins University School of Hygiene and Public Health. 1972-1974, Head, Research Detachment, NAMRU-3, Addis Ababa, Ethiopia. 1974-1976, Commanding Officer, NAMRU-5, Addis Ababa, Ethiopia. 1976-1978, Program Manager, Infectious Diseases Research, Naval Medical Research and Development Command, Bethesda, Md. 1978-1981, Chief of Internal Medicine, Naval Regional Medical Center, Camp Pendleton, Calif. 1981-1982, Director of Clinical Services, Naval Regional Medical Center, Jacksonville, Fla. 1982-1984, Commanding Officer, NAMRU-3, Cairo, Egypt.

Professional Associations. Fellow of the American College of Physicians; Fellow of Infectious Diseases Society of America; Fellow of the Royal Society of Medicine; Fellow of the Royal Society of Tropical Medicine and Hygiene; American Association for World Health; American Medical Association; American Society for Microbiology; American Society of Tropical Medicine and Hygiene; Association of Military Surgeons of the United States; The National Foundation for Infectious Diseases; National Council for International Health; The Professional Association of the Commissioned Corps of the U.S. Public Health Service.

Honors, Awards. Armed Forces Reserve Medal, 1975. Meritorious Service Medal, with Gold Star in lieu of the Second Award, 1976, 1984. Navy Commendation Medal, 1982.

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REPORT ON INTERNATIONAL RESEARCH FELLOWS PROGRAM

Senator WEICKER. Last year the committee asked the Fogarty International Center to prepare a report describing the long-term benefits of the International Research Fellows Program. What are the basic findings of that report?

Dr. WALLACE. That report has been submitted, Mr. Chairman, and it was very encouraging, even more so than we anticipated. We found that the majority of the people in the International Research Fellowship Program—and there have been over 2,000 participants since its inception—have returned to their countries, and almost all have remained in the health arena, more specifically the biomedical research arena. They have contributed significantly to the scientific community of their own countries—generally in the ministries of public health and in academia. They have published in international journals of significance. They have maintained their linkages with scientists at the National Institutes of Health and other research institutes in the United States, and they, themselves, have been responsible for a number of interchanges.

We have further enhanced the report with individual vignettes of a number of scientists. For example, at the present time one of the early fellows has now returned to the NIH as a scholar in residence and is making tremendous contributions internationally in molecular genetics and oncology.

Senator WEICKER. I have other questions for response to the record but I have one more here: I still am not fully convinced in my own mind as to the need for a separate institute. I think there is a need for international program information, everything you do. I have no argument. Why does this have to be a separate institute, why couldn't you be working under the NIH Director in the sense of coordinating among the various other institutes in an international sense, why the separate institute?

Dr. WALLACE. Well, there is no question that I do operate under the Director and I am double hatted in that I am also the NIH Associate Director for International Research. We do, indeed, do a number of things that are concerned with coordination and integration of all international activities of NIH. We also have our own very significant programs. I think you can go back to John Donne some 400 years ago, "no man is an island." We are aware of what the various institutes do internationally and we serve as the focal point on international issues for the NIH. We not only integrate the expertise of the various institutes, but also have expertise within the Fogarty International Center. We are able to use this expertise to facilitate NIH activities in many countries. For example, in China, the National Cancer Institute, the National Eye Institute, and the National Institute of Allergy and Infectious Diseases, all have collaborative research programs. The FIC is the only component of the NIH that is cognizant of all these programs and areas of foreign opportunity.

I could go on with other international examples. We make this our business to really carry on Fogarty's mandate throughout the world. I

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feel that our existence as a separate institute enables the NIH to cut down on what would be a tremendous amount of duplication. We are a resource both within the NIH, for other NIH components and for other Government agencies.

I should mention that part of the Fogarty International Center's mandate is to provide a facility for the assembly of scientists and leaders in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of science internationally as it pertains to health and its implications and applications for the future. I could go on. I would say further that I think we haven't begun to accomplish what is the potential of the Fogarty International Center as an individual center.

Senator WEICKER. Dr. Wyngaarden, I would like to hear your comment as to why this should remain a separate institute.

Dr. WYNGAARDEN. Well, it really isn't an institute: it is a center and it does function as a coordinating center for a great deal of international work that is conducted by all the institutes. If we didn't have it there, we would need the same function in my office under another title.

Senator WEICKER. I can concede that. Do the various institutes have their own relationships abroad, or is it purposely all put over to Fogarty? How does that work?

Dr. WYNGAARDEN. There are many direct linkages between a specific institute at the NIH and a specific foreign laboratory. But all those are coordinated through the Fogarty International Center, and as Dr. Wallace points out, we need some place so that we have a total record of all the interactions. And we need a staff to do this and if not there, I think we would need the same size staff for the same functions. The Fogarty International Center also has a separate and unequal international mandate and a separate set of programs geared to the overall missions of the NIH.

Senator WEICKER. I don't dispute—let me say this right now. I think one of the greatest strengths of the United States lies in our abilities in the sciences, and certainly that is a knowledge that should be disseminated worldwide. I am wondering from an administrative cost point of view whether this is the proper setup, and I gather you and Dr. Wallace are convinced that it is.

Dr. WALLACE. I might point out, too, a further thing, Senator Weicker. One, one-half of our activities and one-half of our funding are for Fogarty International Center's own programs and, further, we do have the mandate of making the international arena available to the other institutes within NIH. I think very often scientists tend to be rather parochial in their views and also in their experiences.

Senator WEICKER. I couldn't help, staff gave me your background here. I must confess, you bring a considerable array of talents to the task. A.B. cum laude, Princeton University. That is an unfortunate choice. [Laughter.]

University of Virginia Law School. Excellent choice. That is where I'm from. M.D. from New York Medical College. As I say, that is quite

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an array of talent. Certainly I am convinced both by performance and by your eloquence of the necessity of continuing the Fogarty Center. Just make sure you don't follow John Donne's other admonition, "I am my own executioner." [Laughter.]

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Thank you very much. There will be other questions for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

INTERNATIONAL RESEARCH FELLOWSHIP PROGRAM

Question: Last year, the Committee asked the Fogarty International Center (FIC) to prepare a report describing the long-term benefits of the International Research Fellowship Program. What are the basic findings of that report?

Answer: For over a quarter of a century the International Research Fellowship Program of the Fogarty International Center has been a major scientific link for the U.S. biomedical research community with other countries and an important source of further development of new postdoctoral investigators in over 50 countries throughout the world. The basic findings of the report are:

- A total of 2,219 fellowship awards have been made to promising foreign scientists in biomedical and behavioral research related to the mission of the NIH.
- Approximately 71 percent of former fellows are engaged in research. By remaining in research, fellows contribute worldwide to the improvement of health and the understanding of disease processes. Additional numbers of former fellows are working in research administration and in important science policy posts in their countries, where they are in touch with NIH and other U.S. scientists and administrators.
- Thirty percent of former fellows continue collaborating and interacting with their U.S. preceptors.
- Former fellows are trainers and mentors of future scientists.
- A total of 185 universities and research institutions in the United States have served as hosts to fellows.
- The success of the International Research Fellowship Program has inspired nine countries to establish similar fellowships for U.S. scientists.

Question: What is the optimum length of time for a fellowship awarded to a foreign scientist?

Answer: Two years is the optimal length of time for an International Research Fellowship. At the outset, the foreign scientist must make living arrangements and become acclimated to a new environment. The purpose of an International Research Fellowship is to initiate and complete a collaborative research project with a U.S. scientist. The conduct of the researcher then requires setting up experiments, verifying and analyzing research results, and preparing data for publication. A 2-year period provides more adequate time to accomplish these objectives.

Question: What percentage of the international fellows receive that amount of support from the Center?

Answer: Approximately 20 percent of the International Research Fellows are granted an extension to their initial 1-year award for

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research fellowship activities and, thus, receive the equivalent of a 2-year award.

TROPICAL RESEARCH/RECENT IMMIGRATION

Question: This country has experienced a significant increase in the immigration of people from regions where tropical diseases are prevalent. Has there been evidence of an increase in the incidence of tropical diseases in this country?

Answer: No; there is no significant increase in the incidence of tropical disease in the United States. However, cases occur and will continue to occur as the result of immigration, refugees who come to this country, and foreign exposure on the part of tourists, military personnel, and others. There have also been epidemics of certain viral diseases in the recent past; such epidemics will continue to pose a threat due to potential spread from Central America. Thus, continuing vigilance and surveillance are important.

Question: Has this affected the research priorities of the Gorgas Institute?

Answer: Yes; viral diseases are a high priority for the Gorgas Memorial Laboratory in Panama. The Laboratory's research and monitoring capabilities located in the natural reservoir for certain of these diseases, such as yellow fever and Venezuelan equine encephalitis, are important to us and other countries because of the real and potential threat of spread. Another important priority is its antimalarial drug testing activity aimed at improving the armamentarium for handling malaria in exposed U.S. citizens as well as others worldwide.

Question: Are we providing them with enough resources to expand their research in tropical medicine?

Answer: The core support provided to the Gorgas Memorial Laboratory through the Fogarty International Center is not intended to provide for expansion of their research in tropical medicine but rather to support the physical and operating infrastructure upon which expansion can take place. Thus, we feel that the amount we provide for core support is adequate. We are encouraged to see recent expansion taking place in that a larger proportion of the Laboratory's total revenue is now being derived from research grants and contracts from sources other than the FIC. Prospects for the next few years also appear favorable. In addition to the efforts of the Gorgas Memorial Institute and Laboratory to expand their programs and support, the Fogarty International Center is also assisting them by sending scientific site-visit teams, which provide guidance on future program direc- tions in specific fields.

RUBELLA CONTROL

Question: I understand that the Institute has been interested in improved control of rubella because cyclic epidemics of the disease occur in a number of nations. What progress is being made in the control and eradication of rubella (German measles) internationally?

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Answer: Both the World Health Organization and the British Commonwealth Secretariat expressed interest and support for the Fogarty International Center to convene an international meeting to examine in depth the potential for the prevention of congenital rubella infection. A number of longstanding scientific questions needed to be addressed, and information was becoming available to resolve these questions.

Progress in the control of rubella and congenital rubella infection in the United States has been profound. At the FIC meeting in March 1984, evidence was presented that the rubella vaccine is safe, highly efficacious, and long-lasting. In 1964, 20,000 infants were born in the United States with the devastating effects of the congential rubella syndrome. During 1983 only 20 cases of congenital rubella were reported in the United States, and only 7 of the affected infants were born in 1983. The complete elimination of congenital rubella infection and indigenous rubella in the United States is now being attempted. It is estimated that between the years 1984 and 2004, the rubella immunization program in the United States will prevent 10,000 cases of sensorineural deafness at an estimated net savings for the United States alone of $2 billion.

Internationally, only a few countries have made significant progress toward eliminating congenital rubella infection. One of the goals of the FIC international symposium was to make recommendations, particularly concerning situations in the developing world, for the improvement of rubella control. At the symposium, various countries considering rubella immunization were advised to embark on rubella immunization programs only after documenting the problem, or the potential threat, of congenital rubella infection by carrying out serological studies on women of childbearing age or on selected groups such as deaf children.

The FIC symposium also concluded that it may be necessary to defer rubella immunization programs where the wild rubella virus (natural infection) circulates freely, enabling children to develop immunity at an early age, and where there are limitations of the health-care system to provide adequate immunizations nationally.

For some nations facing a rubella and congenital rubella problem, the answer may be universal immunization; in other nations, selective immunization may be more appropriate. The highest priority is to protect the population at risk: women of childbearing age.

Question: What vaccine strategy seems to work best?

Answer: Which vaccine strategy works best depends on local conditions and availability of resources. The two most applicable strategies, universal or selective vaccination, have not been totally implemented anywhere. The United States attempted universal vaccination and the United Kingdom selective vaccination of girls age 10-14; the United States is closer to achieving its goal. The cycle of rubella epidemics has been broken in the United States; in the United Kingdom, the impact of its program is only now beginning to be noted.

Question: Is there any hope that rubella can be eradicated entirely?

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Answer: The global eradication of rubella is problematic. The goal of any rubella immunization program is the prevention of congenital rubella infection. Many nations currently lack the resources to interrupt the transmission of the virus and do not possess the capability to protect all women at risk.

As a result of the FIC symposium, a number of nations are reconsidering their rubella immunization efforts. Thus, continuing progress toward control of congenital rubella infection is anticipated.

NEW DIRECTOR

Question: Dr. Wallace, you have been the Director of the Fogarty International Center for a year. What can you tell us about the health of the Fogarty?

Answer: The health of the Fogarty International Center is excellent, and I predict buoyant health in the future. We have gone a long way toward fulfilling the vision of Congressman Fogarty.

The Fogarty International Center has two major purposes, each complementary to the other: first, to build and strengthen our foreign biomedical research linkages; and second, to literally create a center for advanced study in the health sciences. We believe that the first purpose is served through our fellowships, scientist exchanges, and bilateral programs. We are convinced, in specific answer to your question, of the need to strengthen our abilities to be the center for advanced studies that Congressman Fogarty envisioned.

Question: What are your plans for the future of the FIC?

Answer: Aside from strengthening our fellowship and exchange programs and burnishing the coordination and liaison function at all levels, we are planning and envision a true international advanced studies program that would establish eminent scientists as NIH "faculty," in a truly international milieu where advanced studies and concepts would be addressed in a continuous and more vigorous fashion.

Question: Is it fulfilling the vision of Congressman Fogarty?

Answer: Our Scholars-in-Residence Program brings a small number of the best scientists in the world to the NIH for a finite period--this program is moving us toward Congressman Fogarty's vision. We have recently added Dr. Albert Sabin as expert scientist in the International Issues Study-Program to interrelate with the Scholars in our Advanced Studies Program. Enhancing and dignifying these activities as a true "center" would be a total fulfillment of Congressman Fogarty's dreams and, indeed, a manifestation of my own plans for the future of the Fogarty International Center.

FIC ADVISORY BOARD

Question: The Fogarty Institute Advisory Board was created in July 1984 and is charged with improving the exchange of new knowledge and technology between the United States and participating foreign countries, institutions, and scientists. Could you describe the activities of the newly created FIC Advisory Board, and how they may have impacted upon your programs and long-term goals?

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Answer: Secretary Heckler authorized the creation of the Fogarty International Center Advisory Board in July 1984. We are now awaiting the Secretary's signature on letters of invitation to pro- posed Board members. Then, we expect to receive prompt acceptances from Board nominees and to conduct orientations for Board members this summer. We currently plan to hold our first meeting in the fall of 1985.

The functions of the Board will be to provide advice and counsel to the Director of the Fogarty International Center on needs in international biomedical and behavioral research that the FIC might address; long-range plans for the FIC to address relevant issues; periodic assessment of the extent to which FIC programs are meeting their stated goals; and appropriate distribution of FIC resources among its programs to address those goals. The Board will also provide programmatic review and advice regarding applications for research and research fellowship grants supported by the Fogarty International Center.

DISEASE CONTROL

Question: I understand that FIC has made a major effort to focus on the control and eradication of certain persistent diseases in collaboration with the World Health Organization. Please review for us your activities in disease control and eradication programs.

Answer: Almost 5 years ago, in May 1980, the Center invited infectious disease experts to come to the National Institutes of Health to explore the possibility that selected infectious diseases could be subject to improved control and potential eradication, similar to that marvelous medical and political achievement, the global eradication of smallpox.

The results of that gathering of international experts, published in the Reviews of Infectious Diseases, of September-October 1982, advised that of the 15 disease candidates examined, measles, poliomyelitis, and yaws were clearly suitable for at least regional eradication. The report also stated that the "study of the desirability and feasibility of regional and global eradication of these diseases is recommended to the Fogarty International Center."

Acting upon these recommendations, the Center organized three international symposia in collaboration with the World Health Organization to study in detail the problems and opportunities associated with these three quite different diseases, all of which are dissimilar to smallpox. In March 1982, a meeting was held on measles, followed a year later by a symposium on poliomyelitis, and in April 1984, a conference was convened on yaws. The site for all three meetings was the World Health Organization's Regional Headquarters for the Americas in Washington, D.C.

The results of these meetings and the momentum generated are expected to continue for a number of years. The concept and the inherent problems of global eradication were addressed. For paralytic poliomyelitis the consensus involving most of the world's experts in this field present at the symposium was that eradication was feasible but remains a distant goal. A surprising result of the conference was discovery of the magnitude of the polio problem: 65 percent of the world's nations are burdened with this disease.

The consensus reached at the symposium on measles was that "there is no known biologic reason why successful measles immunization cannot be extended to all the world's children . . . measles can be eliminated as a universal cause of childhood and of long-term disabilities." Problems of administration and delivery of the vaccine remain to be overcome.

Another problem highlighted at the symposium was that as various nations achieve measles control within their own boundaries, the problem of importations of the disease from countries where immunization programs are less successful, or nonexistent, will become more apparent and increasingly troublesome. The members of the symposium also noted that a more overt commitment to measles control is needed in the nations of the developing world.

Dr. Albert Sabin, long recognized for his contributions to poliomyelitis research and disease control, has also turned his attention to measles. Dr. Sabin has recently joined the Fogarty International Center and is assisting the Center in following up on recommendations stemming from the measles conference. He is particularly devoting his attention to a better means of introducing the vaccine in the developing world. Dr. Sabin is making important contributions in this area: he and his colleagues have reported in the May 1984 issue of the Journal of the American Medical Association that clinical trials in Latin America involving the use of the human diploid cell lyophilized measles aerosolized vaccine successfully immunized very young children (4-6 months old). This is considered significant because, in the developing world, measles takes a high toll of children under 1 year of age.

Experts at the international symposium on yaws and other endemic treponematoses advised that timely action is needed. These closely related diseases are curable by a single injection of long-lasting penicillin; resistance to penicillin has not yet developed in the causative spirochete, and it is scientifically difficult to ascertain if, or when, resistance to penicillin could develop, as has happened in other bacteria. The conference documented the resurgence of yaws in many countries, particularly in West Africa. The estimate of cases exceeds 1 million. To bring these diseases under control will require adequate resources available on a regional basis and a concerted effort on the part of governments and international organizations.

The Fogarty International Center is acting on this recommendation and, in consort with CDC, WHO, and UNICEF, will convene an interregional meeting in July in Indonesia to foster control programs against yaws. Representatives of the ministries of health of Indonesia, India, Solomon Islands, Papua New Guinea, Malaysia, Sri Lanka, Thailand, and Saudi Arabia are expected to participate. A similar meeting is planned in Brazzaville, Congo, in November 1985 for the African region.

INTERNATIONAL ISSUES

Question: The International Issues Study Program focuses on international public health issues such as the eradication of certain diseases, the increase of antibiotic-resistant microorganisms, and biotechnology transfer. What is presently on the agenda of the International Issues Study-Program?

Answer: The International Issues Study-Program is actively addressing a number of international public health issues. As a follow-up to an international conference on yaws and other endemic treponematoses held in April 1984, the program is working with the Centers for Disease Control, the World Health Organization, and other international organizations to develop regional strategies for improved control. A meeting on this subject will be held in July 1985 in Indonesia involving representatives from nations in the Western Pacific, Southeast Asian, and Eastern Mediterranean regions. A similar meeting involving the African region is scheduled for November 1985.

In September 1984 six workshops were held addressing the use of antibiotics worldwide. The task forces are continuing their year-long studies, and final reports are expected in September 1985. These reports will contribute to the background information for an international symposium dealing with antibiotics scheduled for March 1986. This symposium will address the issue of antibiotic-resistant organisms and other scientific matters of interest to the NIH.

In July 1984 the International Issues Study-Program was fortunate to have Dr. Albert Sabin join the Center as a senior expert consultant. Dr. Sabin is coordinating follow-up work relating to two previous international conferences dealing with the improved control of polio and measles. Dr. Sabin has been working with Rotary International and the World Health Organization to develop improved and innovative strategies to prevent death and disabilities from childhood infectious diseases.

The Fogarty International Center has also been most fortunate to have Sir John Wilson as a Fogarty Scholar-in-Residence. Sir John has been a major figure in worldwide efforts to prevent disabilities, particularly blindness. While at NIH, Sir John is developing research and implementation strategies to effectively reduce the burden of disabilities around the world. Last March he held a workshop to develop better estimates of the impact of disabilities including blindness, deafness, and orthopedic handicaps.

Much of the work of the Advanced Studies Program has benefited from the marvelous advances that have been made in the area of biotechnology. In November 1984 a major international conference, attended by 1,300 scientists, was held on the subject of oncogenes, cell growth, and cancer. In March 1985 a conference was held dealing with metastases. Also in March a conference was conducted on plasminogen activator genes. In April 1985 a conference will be convened on the subject of DNA methylation. These conferences have been organized by Fogarty Scholars-in-Residence and supported by the staff in the International Issues Study-Program.

Future activities of this program will be selected from a number of issues related to international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to benefit international health.

Question: The interaction of the international community of biomedical research scientists with the NIH is one of our most potent vehicles in bringing the advances of modern biomedicine to the world. What role does your Institute play in this area?

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Answer: The overall mission of the Fogarty International Center is to promote international cooperation in all aspects of the health sciences. This is accomplished in a variety of ways, including:

- Coordination of international activities of the NIH, including management of some 55 bilateral agreements with 32 countries, and providing liaison between various NIH components and scientists and other organizations elsewhere.

- The Advanced Studies Program, which provides opportunities for biomedical and behavioral scientists throughout the world to share knowledge, ideas, and concerns about international health.

- The Scholars-in-Residence Program, which enables world-renowned scientists from the United States and abroad to interact on the NIH campus through workshops and seminars and the performance of collaborative research with NIH intramural scientists.

- Sponsorship of the Senior International Fellowship Program, which enables established biomedical scientists from the United States to study abroad and to share their expertise with foreign counterparts.

- The International Issues Study-Program, which conducts special policy studies in a variety of areas relevant to biomedical and behavioral sciences worldwide.

- Dissemination of information on NIH's biomedical research programs and accomplishments to foreign scientists and research institutions.

BILATERAL AGREEMENTS

Question: Please review significant bilateral agreements between FIC and foreign countries.

Answer: The Fogarty International Center has lead responsibility for coordinating scientific activities under 55 agreements with 32 countries in which the NIH participates. A complete account of collaboration under each of them would be voluminous, but a few examples will serve to illustrate the scope of involvement:

- The oldest bilateral agreement is the US-Japan Cooperative Medical Sciences Program, signed in 1965 and covering a broad range of research on parasitic and viral diseases, environmental health, and malnutrition. The NIH also participates in five other agreements with Japan covering activities in cancer, vision research, cardiovascular diseases, laboratory animal science, toxic chemical effects, biomedical information science, and gerontology.

- The NIH has an extensive cooperative program with China under the US-PRC Health Protocol, which was originally signed in 1979. The 10 areas covered under this agreement are infectious and parasitic diseases; cancer; cardiovascular disease; public health and health services research; biomedical information science; immunology; human genetics; reproductive

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physiology and family planning techniques; mental health; and food and drugs. The NIH participates in eight of these areas. Other PHS agencies involved are CDC, FDA, and ADAMHA.

- o NIH also cooperates very actively with India under the Indo-US Joint Commission on Economic, Commercial, Science and Technology, Educational, and Cultural Cooperation, signed in 1974. In addition, we are involved in the special Science and Technology Initiative established by President Reagan and the late Prime Minister Indira Gandhi in 1982. These activities focus on vision research, infectious diseases, and reproductive physiology.

- o In Europe, some of our most productive and mutually beneficial programs are carried out under bilateral agreements with Spain, Italy, and France.

RESEARCH ON DISEASE PREVENTION

Question: In a speech before the American Pharmaceutical Association Dr. Wyngaarden said that 28 percent of NIH funds are directed to research in prevention of disease. What types of disease prevention research are being done by your Institute?

Answer: Research in disease prevention is carried out in the Advanced Studies Program, in both the Scholars-in-Residence and the International Issues Study-Programs. A number of individual scholars spend part of their time assembling the available research results into plans for action at the international public health level. An example is in the area of preventable disability where existing medical technology needs to be organized on a mass scale in order to reduce the crippling effects of poliomyelitis and to prevent deafness resulting from middle ear infections, brain damage caused by inadequate protein intake during fetal life and early infancy, or mental retardation that frequently follows measles in the first 5 years of life. In the series on eradication and control of infectious diseases, projects in prevention, control, or eradication of measles, poliomyelitis, yaws, congenital rubella, typhoid fever, and rabies have been completed or are underway. In addition to the activities of the Fogarty International Center, the Gorgas Memorial Laboratory in Panama, which receives core funding through the appropriation of the FIC, is conducting research in cancer epidemiology, Chagas' disease and other tropical diseases, insect genetics, and various insect and rodent diseases that can be transmitted to humans.

Question: What percent of your budget is directed to research on prevention?

Answer: We estimate that almost half the appropriation for the Fogarty International Center, including that which is made to the FIC for the Gorgas Memorial Laboratory in Panama, is devoted to prevention of diseases worldwide.

Question: How are the results of this research being translated into useful public information?

Answer: The reports that result from a scholarship awarded in the area of preventable disability are being used by national and international agencies in formulating plans for action. A recent

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example is in Burma where plans formulated by a Fogarty Scholar-in-Residence at NIH are being translated into a plan for action to reduce deafness. Practically all our Scholars-in-Residence appointments and our special issues studies include the conduct of major international conferences, bringing together scientists from throughout the United States and from abroad. For example, our recent conference on oncogenes had an attendance of about 1,300 participants from many countries. Some of our conferences also have participants from other public sectors. Our present task force meetings on the use of antibiotics worldwide include members of the pharmaceutical industry and public interest groups, as well as scientists. All these events are subsequently published in appropriate journals for wide dissemination.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: Administrative costs for grant review and administration are being addressed through increased use of computer processing, electronic distribution of information needed for the review and award process, and employment of other technology to reduce the storage and mailing of a large volume of printed matter.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer: We have initiated a series of in-house management studies to review, in turn, all our program areas. Those that we have completed have revealed a number of inefficiencies or resource imbalances that we have corrected. We have also identified needed improvements in a computer-based personnel processing system and are developing approaches to implement them.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: We have instituted a system of cost review. Senior staff of the Center are regularly reminded of our fiscal situation, and have been urged to pay particular attention to cost-benefit considerations when committing resources.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: The withholding and the proposed rescission of a portion of our budget in 1985 has not affected the review process or the procedures used to make decisions about our awards. Other areas have borne all the effects of that cost containment.

FRENCH/CUBAN COOPERATION IN TROPICAL MEDICINE

Question. I received a letter from the Gorgas Memorial Institute describing a new collaboration between France and Cuba expanding the Institute of Tropical Medicine in Havana. Is there anything you can tell us about this agreement?

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Answer. On January 9, 1985, an announcement from Havana described two initiatives between France and Cuba which resulted from the Sixth Joint Technical-Scientific and Cultural Commission meeting held from January 7 to 9, during which the French Minister of Cooperation and Development, Christian Nucci, met with President Fiedel Castro. The first project is the establishment in Havana of a French Cultural Center which should provide for "a dialogue of the two cultures." The second project concerned French participation in the expansion of the Institute of Tropical Medicine in Havana. According to the initial announcement, the French were expected to provide for the following: laboratory equipment, fellowships for specialist training, and the organization of technical assistance missions.

According to the Department of State, a French-Cuba agreement has been signed which would link the Cuban Institute of Tropical Medicine with French researchers in areas of immunology and clinical biology. No specific French institution was identified in this agreement; no further details are available.

Question Submitted by Senator William Proxmire

CANCER IN CHINA

Question: Dr. Wallace, on page four of your prepared statement you say that China's recent completion of a comprehensive national cancer mortality survey provides a unique opportunity to gain information on potential causes of cancer. Could you elaborate on that statement by telling us if NIH is supporting any work using that data base? When might we begin to see the results of analyses of cancer causation using the Chinese data base?

Answer: The Chinese Ministry of Public Health conducts regular periodic geographic surveys of cancer mortality. Based on information derived from the latest mappings, the National Cancer Institute has initiated four studies: a large-scale nutrition intervention investigation and three case-controlled studies of esophageal cancer, lung cancer, and choriocarcinoma. Some of the data analyses will be completed by the end of 1985, and the remainder are expected to be completed by the end of 1986.

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NATIONAL LIBRARY OF MEDICINE

STATEMENT OF DR. DONALD A.B. LINDBERG, DIRECTOR

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

KENT A. SMITH, DEPUTY DIRECTOR, NATIONAL LIBRARY OF MEDICINE

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. Next we will hear from Dr. Donald Lindberg, Director of the National Library of Medicine. The library is the Nation's primary source for biomedical information and is in the forefront in developing technology to store or distribute that information.

The library's request for fiscal year 1986 is for $53.3 million. Dr. Lindberg, please proceed. Your statement in its entirety will be placed in the record.

[The statement follows:]

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Statement of Dr. Donald A.B. Lindberg

Mr. Chairman and distinguished members, I am pleased to appear before you today as the Director of the National Library of Medicine. I have watched this remarkable institution grow and mature through the years, and have served on its advisory bodies. To have the opportunity to guide the Library into the twenty-first century is both rewarding and challenging.

Health professionals increasingly depend on sophisticated retrieval systems to provide rapidly the information they require for health care, research, and education. The National Library of Medicine has traditionally been a leader in developing such systems. I believe that today we are poised at the threshhold of an era that will see our health professionals have virtually unlimited access to needed information and heuristic knowledge. That is, they will be able to extract from the published literature precisely the right piece of information and to obtain automated consultation on how to use it for medical problem solving.

To realize this potential, the Library is exploiting the most modern technology--

- o microprocessors, as workstations within the Library and as targets for downloading information to health professionals around the nation;
- o communications networking technology, which makes available a growing variety of NLM online databases;
- o optical discs, a medium of information storage that shows great promise for image and full-text retrieval; and
- o artificial intelligence techniques as a means to discover new techniques for formal representation of knowledge and to model with computers the cognitive processes of the medical specialist in giving expert consultation.

For NLM, the road toward use of these amazing modern technologies began in 1836 with an appropriation for a small collection of professional books in the Library of the Surgeon General of the Army. By 1879, John Shaw Billings had issued the first edition of the Index Medicus. The direct successor of the unit, the National Library of Medicine, will be 150 years old in 1986.

Reflecting this proud history and the uncharted potential for future development, the Board of Regents of the Library

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have instructed me to initiate two special activities this year: first, to plan a suitable observance of the NLM Sesquicentennial, and second, to work with the Library and the various groups it serves to make a long range plan for progress over the next 20 years, and a detailed plan for our efforts during the coming 5 years. I look forward with pleasure to reporting to you next year on both activities.

Extramural Programs

The NLM's extramural budget, authorized under the general research authority of the PHS Act and the original Medical Library Assistance Act of 1965, has grown to $12.2 million in FY 1985. In 1985 we expanded our support for two high-priority programs: IAIMS and Medical Informatics.

The Integrated Academic Information Management Systems (IAIMS) program stemmed from a 1982 recommendation of the Association of American Medical Colleges; NLM support began in FY 1983. This initiative is an effort to create model computerized information systems that will serve health professionals in complex academic health centers. From a single desk top terminal, there will be rapid access to various files and systems: patient records, laboratory tests and results, the professional literature through systems such as NLM's MEDLARS, remote files such as a tumor registry in another state, clinical decision-making systems such as those being developed under NLM's medical informatics program, student records, and communicating with colleagues. A number of small planning awards were made in FY 1983 and FY 1984, and in FY 1985 awards were made for development of selected portions of the systems as feasibility tests.

Medical Informatics is a research program NLM has supported for over ten years. As an investigator at the University of Missouri, I myself have conducted research in this area under NLM and other support. I can attest to the importance of even modest public support for primarily medical uses of this new technology to match partly the much larger pool of funds that support application of this same technology for industrial robotics, petroleum exploration, and military missile command and control. Medical Informatics is a multidisciplinary field, involving the integration of computer and information sciences, medicine, engineering, and management science. The ultimate goal of such research is to develop computerized systems with which human users may consult interactively--much in the same way that physicians and scientists now consult with their colleagues--to improve medical care and medical decision-making and to enhance scientific discovery. Support by the Library for investigator-initiated Medical Informatics research has increased recently--from $1.9 million in FY 1984 to an estimated $3.8

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million in FY 1985 and approximately the same at the FY 1986 request level.

Creation of a Unified Medical Language System

In FY 1985, the Library has begun a ten-year project to address a most fundamental problem in medical informatics: the lack of a unified standard medical vocabulary. Working with the American Medical Association, university investigators in academic departments, health professional associations, and federal collaborators, NLM hopes to coordinate a program to create such a medical language. The development of a unified medical language is an important step in enhancing medical communications and should assist in the common goal of developing a more cost effective national health care system.

Intramural Programs

Library Operations is the component responsible for NLM's basic mission--to build, maintain, and provide access to the world's largest collection of biomedical literature in support of progress in medicine and the improvement of public health. In FY 1984, 306,000 articles were indexed for MEDLINE. NLM's online system was searched for over 229,000 hours, which equate to an estimated 2.4 million online searches performed for health care professionals and researchers outside our institution; NLM databases mounted on commercial and foreign computer systems were used for over 196,000 additional hours; 147,000 interlibrary loans were filled by NLM, 26,000 patrons made on-site use of our facility, and 94,000 books and other items were added to NLM's collection of over 3 million items.

The two principal products of NLM are Index Medicus, the premier printed bibliography of medical literature in the world, and the approximately 30 online databases and datafiles that together make up MEDLARS (Medical Literature Analysis and Retrieval System). NLM computers provide access to MEDLARS through online searches coming through the Regional Medical Library Network of 3,000 U.S. hospitals and through 7 overseas online MEDLARS centers and 7 MEDLARS tape centers. In addition, MEDLARS tapes are also leased by domestic commercial firms who then provide online access through their own computers here and abroad. NLM user fees recover the full cost to access MEDLARS, and as of April 1, 1985 foreign users of NLM's databases will be charged their full share of the costs of creating the databases as well.

NLM is continually striving to improve its products and services. An example is the development of subsets of the MEDLINE database now available by lease to users for mounting locally on their personal or institutional computers. These subsets also provide the opportunity for private sector

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information providers to market new value-added services. In FY 1985 NLM is establishing such collaborative programs with commercial information vendors to create new and innovative products and services.

The Lister Hill National Center for Biomedical Communications is NLM's intramural research and development component. Established by Congress in 1968, the Center is performing research in a number of promising areas including two I previously mentioned--laser disk applications and the development of a unified medical language. Other research directions include: research in knowledge representation with computer-based systems; examination of methodologies for electronically organizing machine-readable databases to increase the productivity of NLM's indexing and cataloging; and development of prototype computer-assisted instructional materials for medical education that make use of question-and-answer interaction, including high-quality video images to dramatize the patient findings and management problems.

The Toxicology Information Program (TIP) is NLM's intramural program to provide specialized information services in the areas of toxicology and environmental health. The computerized databases created and provided by NLM are an important link in the National Toxicology Program and other interagency collaborative efforts. Using "Superfund" monies, TIP is developing a microprocessor-based workstation that could be used immediately to retrieve necessary information by emergency response teams at the site of a chemical spill or accident.

Summary

In conclusion, Mr. Chairman, as one who has only recently joined the Federal service, I would like to make a personal observation. Within the academic community and within medicine generally, the National Library of Medicine is held in the highest esteem. It is seen not only as the home of the world's pre-eminent collection of health-sciences literature, but it is famed for its innovative health information services. I can say this only because the credit for the Library's accomplishments belongs elsewhere.

I believe that those who have gone before me have set this institution in the right direction to take maximum advantage of the opportunities before us. The Library's extramural and intramural programs are soundly organized and will continue to contribute to improving the access of our health professionals to biomedical information.

Mr. Chairman, the request for the National Library of Medicine for FY 1986 is $53,320,000, a decrease of $1,088,000

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from estimated comparable obligations in FY 1985. I shall be pleased to answer questions.

Biography of Dr. Donald A.B. Lindberg

September 21, 1933. New York, New York

Education: A.B., Biology, Amherst College, magna cum laude, 1954; M.D., College of Physicians and Surgeons; Columbia University, 1958; Sc.D., Amherst College, (hon. caus.) 1979.

Professional History: 1984-present, Director, National Library of Medicine; 1971-1984, Director, Information Science Group, University of Missouri School of Medicine; 1969-1984, Professor of Pathology, University of Missouri School of Medicine; 1976-1980, Director, Health Services Research Center with Special Emphasis Health Care Technology Center, University of Missouri-Columbia; 1972-1973, Consultant for Health Sciences to Vice President for Academic Affairs; 1969-1971, Professor and Chairman, Department of Information Science, University of Missouri School of Library and Information Science; 1970-1971, Staff, Vice President for Academic Affairs, University of Missouri; 1967-1970, Director, Regional Medical Program Information Systems; 1968-1970, Staff, Executive Director for Health Affairs, University of Missouri; 1962-1970, Director, Medical Center Computer Program, University of Missouri; 1967-1969, Director, Missouri Regional Automated Elecrocardiography System; 1966-1969, Associate Professor of Pathology, University of Missouri School of Medicine; 1963-1966, Assistant Professor of Pathology University of Missouri School of Medicine; 1962-1963, Instructor in Pathology, University of Missouri School of Medicine; 1960-1963, Director, Diagnostic Microbiology Laboratory, University of Missouri Medical Center; 1960-1962, Resident Physician in Pathology, University of Missouri School of Medicine; 1959-1960, Assistant Resident in Pathology, Columbia-Presbyterian Medical Center; 1958-1960, Assistant in Pathology, Columbia University College of Physicians and Surgeons; 1958-1959, Intern in Pathology, Columbia-Presbyterian Medical Center; June 1955-Sept. 1955, June 1954-Sept. 1954, Research Assistant to Dr. O.E. Schotte, Amherst College.

Honors: Phi Beta Kappa; Simpson Fellow of Amherst College (1954-55); Markle Scholar in Academic Medicine (1964-69).

Professional Memberships: Sigma Xi; American Society of Clinical Pathologists; College of American Pathologists (Telecommunication Network Committee, Committee on Emerging Technology); Missouri State Medical Association; American Association for Advancement of Science; Association for

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Computing Machines (SIGBIO); Salutis Unitas; American Association for Medical Systems and Informatics, Board of Directors; Symposium on Computer Applications in Medical Care, Board of Directors; National Board of Medical Examiners, Board Member; Washington Society for the History of Medicine; Editor: Information Methods in Medicine, Journal of Medical Informatics, Lecture Notes in Medical Informatics, and Journal of Medical Systems; National Academy of Practice in Medicine Distinguished Practitioner; Computer Science and Engineering Board, National Academy of Sciences (1971-1974); U.S. Representative to International Medical Informatics Association, and Trustee (1975-1984).

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SUMMARY STATEMENT

Dr. LINDBERG. Senator Weicker, I should like to touch only very briefly on certain portions of my written statement. To do this, I will summarize our ongoing commitments and then turn to new research initiatives.

During the past year the National Library of Medicine has continued to build and maintain its position as the largest and finest biomedical library in the world. In 1984, 153,000 physical items were added to a collection of 3 million. Three hundred thousand scientific articles were indexed and added to its on-line computer data bases. The U.S. Biomedical Communications Network was maintained with support to its seven regional medical libraries. The network also has 125 resource libraries, its 3,300 local biomedical libraries. Three million on-line computer inquiries were processed automatically and 87,000 highly specialized inquiries were handled personally by staff.

Medlars centers in 14 foreign countries were maintained and coordinated, and assistance was provided to 2 additional countries that wish to make Medlars centers. In addition, major enhancements were made to the NLM toxicology information system in collaboration with the FDA and EPA.

Senator Weicker, the things I have mentioned are not merely traditional library functions. These are the most advanced library services of the best biomedical library in the world. But these are not enough. The commendable advances and concepts in diagnoses and treatment which stem from NIH and elsewhere which we have heard about all week, are not helpful to the individual patient unless they are known to, available to and used by the health professional who takes care of that patient. Increasingly nowadays, professionals need and demand help from a more active kind of information system. The research initiatives of NLM are aimed at development of such systems: that is to say, systems which can deliver scientific information when and where it is needed.

In this category, the advanced systems under development attempt to provide information from the biomedical literature and integration in integrated form of other activities of a minor complex medical center, namely recording of patient care information, the medical information teaching and the management activity, integrate all those together. And this program is called IAIMS, integrated academic information management systems.

In addition, the very most advanced research systems under development attempt to go even further. These attempt to use artificial intelligence techniques to imitate the consultation and advice-giving behavior of a medical expert with respect to diagnosis and management.

I should point out that the programs work only in limited areas. They can't handle all of medicine as yet, but what they do, they do very well. This is advice that can only be given by a top human expert. There are not enough of them. Therefore, their advice is not sufficiently widely available. This activity is part of the Medical Informatics Extramural Grants Program and original research in this field is also done in Lister Hill Center of NLM.

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The last NLM research initiative to which I wish to draw attention is the unified medical language system. Mr. Chairman, the most fundamental obstacle to the optimal use of computers in medicine has for 20 years been the lack of a standard vocabulary and terminology. A number of attempts to solve this problem have failed. I believe, nonetheless, that now is the time to establish such a system and that NLM is the right institution to take the lead in this development. Consequently, we have begun a feasibility study, funded out of current 1985 appropriations, to see if we can develop a system that will link the terms used to describe clinical findings and treatments with the terms that are used to index and access the biomedical literature. The linkages will extend further to the teaching and management activity of medicine as well.

So far, our experiments indicate this can be done, provided we collaborate and cooperate with relevant interested groups. These groups include the AMA, the medical specialty societies, university researchers, commercial insurance companies, and interested Federal Government experts.

Mr. Chairman, in 1986 NLM will be 150 years old. I wish to assure the committee that NLM is held in the highest regard in the United States and internationally. Given a chance, it will contribute in a major way to progress in basic science, clinical medicine, and improved health care. I will be happy to answer questions.

OREGON HEALTH SCIENCES UNIVERSITY PROJECT

Senator WEICKER. Thank you very much.

In 1983, Congress provided $5.9 million to establish a Biomedical Information Communications Center at the Oregon Health Sciences University. What is the status of that project?

Dr. LINDBERG. The IAIMS programs were designed to be implemented in three phases: namely, a planning phase, a development phase, and a third prototype building phase. We received an application from the Oregon Health Sciences University for a planning award and that was funded. It is in its second year. That was in the amount of $495,000. At the end of the first year, they requested an extension to 2 years. This was not unusual. Other schools have found it requires 2 years to go through a planning phase. So that is where it stands at the moment.

One would expect to receive an application to bring that institution into the development phase.

Senator WEICKER. Is the $5.4 million being proposed for transfer part of the original $5.9 million for the Oregon Health Sciences Center?

Dr. LINDBERG. My understanding is that it is the administration's position that the unobligated balance of $5.4 million will be transferred to the Office of Human Development Services.

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APPROPRIATION LANGUAGE

Senator WEICKER. For the third year in a row, new appropriation language is being proposed for NLM that would allow receipts from services to be credited to the regular appropriation. This committee has rejected such language in the past. Is there any reason to treat a public institution like the NLM as if it were a commercial operation?

Dr. LINDBERG. I think the language is part of the administration's general view to encourage the collection of fees for service. In the particular case of NLM, the fees for use of Medline services have been collected in the past in a way perfectly satisfactory to us, through the National Technical Information Service.

CENTERS OF EXCELLENCE IN MEDICAL INFORMATICS

Senator WEICKER. Both NLM and this committee have expressed the belief that centers of excellence in medical informatics should be established in some of our country's best academic institutions. Why are you not asking for funding to continue this important program?

Dr. LINDBERG. Compatible with the administration's view that budget reduction is a top priority and that holding the line on budgets is an important thing this year, we have not proposed to initiate this important program in 1986.

BIOETHICS CENTER

Senator WEICKER. Can you bring us up to date on the National Reference Center for Bioethics, have you made the award yet?

Dr. LINDBERG. As you know, the funds were made available this year for the National Reference Center you refer to and we made a solicitation for proposals. These are in hand and are being reviewed at this moment. An award has not been made but will be expected shortly.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much. I have further questions for response to the record. Thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

INTEGRATED ACADEMIC INFORMATION MANAGEMENT SYSTEMS (IAIMS)

Question: We understand that NLM has begun support for the second phase--development of prototypes--of the Integrated Academic Information Management Systems (IAIMS) Program. How much has been budgeted for IAIMS in FY 1985?

Answer: A total of $2,500,000 has been budgeted for IAIMS in FY 1985 to support planning and model development.

Question: What is the effect of the FY 1986 budget request on this program?

Answer: The FY 1986 budget will provide for current planning and development projects and the implementation phase will be deferred.

Question: How soon will a system of this nature be in everyday use by: 1. faculty in a medical institution;
2. physician in his office?

Answer: It must be emphasized that the IAIMS concept is experimental. An institution's ability to create such integrated systems requires effective research in the application of computer and communication technologies, adequate financial resources, organizational adjustments and ideally the creation of a unified medical language. An estimated 8 year period is necessary to bring an institution through strategic planning and model development to an operational prototype state. For future IAIMS centers, it is anticipated that this period will be compressed since experiences of current awardees will be shared with these future centers.

It is assumed that utilization by faculty in a medical institution and by affiliated physicians in offices should be available simultaneously. Some portions of this capability will become available during the development phase.

Question: How much funding will be necessary in FY 1986 to continue development of this program?

Answer: The 1986 budget will provide for all ongoing planning and development projects. Progress of current awardees and national acceptance of IAIMS has exceeded expectations.

FY 1985 PROPOSED TRANSFER

Question: In 1983 Congress provided $5.9 million to establish a Biomedical Information and Communications Center at the Oregon Health Sciences Center. Why are you proposing transfer of $5.4 million?

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Answer: The unobligated balance of $5,405,000 is proposed for transfer in FY 1985 to the Department's Office of Human Development for adoption assistance activities.

CENTERS OF EXCELLENCE
IN MEDICAL INFORMATICS

Question: What will you lose in the way of momentum by not funding a Centers of Excellence program in FY 1986?

Answer: The concept of Centers of Excellence in Medical Informatics, delineated for the record at last year's hearing, addresses the need to provide a stable mechanism for comprehensive training of highly skilled career investigators, adequate core research funding, and career development programs for experienced investigators. The Centers of Excellence concept has not as yet been implemented.

Question: How much funding would be necessary to continue this program in FY 1986?

Answer: To begin a viable program in Centers of Excellence in Medical Informatics I believe we should support a minimum of four such centers. Total cost in the first year would be about $3.2 million, an average of approximately $800,000 per center.

BIOETHICS

Question: How will the new National Reference Center for Bioethics interact with the established Center for Bioethics at Georgetown University?

Answer: The award for the new national center will be made competitively in FY 1985. Georgetown University has submitted an application, along with other institutions. Because the new award has not yet been made, I cannot tell you the nature of the interaction with the existing Georgetown award which we are committed to support through FY 1986.

UNIFIED MEDICAL LANGUAGE

Question: I note that on page 351 of your justification you place a high priority on a proposed unified medical language system which you say would have far-reaching effects upon the health community. Please elaborate upon this proposal.

Answer: In FY 1985, the NLM has begun a program to address a fundamental problem in medical informatics: the lack of a unified standard medical vocabulary. For decades the major fundamental impediment to widespread adoption of computer-based information systems in medicine has been the absence of standard vocabulary, terminology, definitions, and criteria for recording the results of biomedical research, the

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events of clinical patient care, and the managerial and business transactions of hospitals.

Question: Who would be the participants in its development?

Answer: Working with the American Medical Association, university investigators in academic departments, health professional associations, and federal collaborators, NLM hopes to coordinate a program to create a unified medical language. This program would be guided by an advisory committee whose members include these groups and also insurance industry and relevant governmental agencies.

Question: What are the anticipated costs?

Answer: The NLM, through its Lister Hill National Center for Biomedical Communications, has begun with a modest initial investment of approximately $300,000 in FY 1985 to explore how such a universal language can be created. As funding becomes available the implementation of the feasibility study can be initiated. This effort is comparable in magnitude to the development of NLM's MEDLARS system.

Question: What would be the benefits?

Answer: A major benefit will be the utility of a physician writing a patient record to use the terms that describe the patient's findings, be they symptoms, signs or diagnoses, as a direct means to obtain access to the published scientific literature and reports about the findings. This ability to link the care of an individual patient to automated library resources will tend to reduce in a major way the gap between what is known and what is practiced.

Similar benefits will be seen by students of medicine and other health care professionals when the vocabulary of practice is well linked with the terms used in instructional activities.

MEDICAL INFORMATICS RESEARCH AND TRAINING

Question: In last year's testimony reference was made to a National Science Foundation study regarding computing in higher education. It indicated that other nations have recognized the role of computing in their national plans and are investing in research and training on a scale not found in the U.S. How is the NLM program in Medical Informatics research and training addressing this problem?

Answer: While we have been able to increase funding for Medical Informatics research to $3.8 million in FY 1985 and FY 1986--compared to about half that amount in FY 1984, the training of skilled investigators in this complex and highly specialized field remains a problem. In FY 1986 we

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could support 28 trainees, compared to the 91 supported ten years ago in FY 1976. The concept of Centers of Excellence in Medical Informatics, described at last year's hearing, addresses the need to help universities to strengthen their formal academic training programs in medical informatics. Centers of Excellence would provide a mechanism for comprehensive training of career investigators, adequate core research funding, and career development programs for experienced investigators.

REDUCTION IN FULL-TIME EQUIVALENCY
STAFFING LEVEL

Question: We note that the NLM full-time equivalency position level decreases by 22 compared with the 1985 Congressional ceiling. What effect will this have on NLM's ability to provide medical information services to the health community?

Answer: NLM has been able, in the past, to keep with steadily increasing workloads through the aid of automated systems, particularly in labor intensive library processing activities. We will continue to provide effective services to the biomedical community, however, there may be slight delays in cataloging and indexing which could slow the availability of the latest published research results to the nation's biomedical community.

Question: This Committee is continually concerned about the effective dissemination of new medical research findings. The Library has a major role in this effort yet the services of NLM are not known by all who could benefit from them. Will your 150th anniversary provide an opportunity to make your services better known to the public and the biomedical community.

Answer: I share your concern that the Library's services are not as widely known as they should be throughout the medical community. Too often I meet professional colleagues who are unaware that they can have direct access to millions of references and abstracts from the medical literature, or that a copy of the actual article can be obtained through a nationwide network of Regional Medical Libraries.

Your observation about the Library's 150th anniversary in 1986 is quite correct. It will afford us the opportunity to make our services better known to the professional community. With the strong support of the Library's Board of Regents we plan to begin an educational outreach program to let health practitioners, researchers, and educators know of the information resources available to them through their National Library of Medicine. I am confident that through a modest expenditure of resources we can dramatically increase professional awareness of the Library and its services, and thereby significantly aid the process of translating the results of research advances to the health providers.

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ARTIFICIAL INTELLIGENCE

Question: Each year we hear more and more about the effective application of artificial intelligence in medical diagnosis and treatment. What is the state of this technology and where is research being conducted in this area?

Answer: A number of artificial intelligence (AI) based diagnostic programs have been developed. Most deal with narrow domains of medicine such as antibiotic selection, oncology protocols, rheumatic disorders, disorders of blood coagulation, acid-base balance, etc. Early testing of some of these programs have shown them to be as accurate as a consensus of experts and more accurate than any individual expert. Further testing is now required to be sure that they operate with equal effectiveness in environments other than the one in which they were created. Such testing is now being undertaken. Allied with this testing is an investigation into the "acceptance and use" of these programs initially by experts other than those involved in their development and then by the non-expert.

AI research of this type is conducted at the National Library of Medicine and supported by the Library at a number of universities. These include M.I.T., Tufts, Harvard, Yale, Rutgers, Pennsylvania, Pittsburg, Maryland, Ohio State, Minnesota, Missouri, Utah, Stanford and the University of California at San Francisco.

RESEARCH ACCOUNTABILITY ACT

Question: Is there any estimate of what it would cost to implement Representative Torricelli's "Research Accountability Act" which proposes to reduce duplication of experiments using animals?

Answer: An initial estimate of resources required to implement the provisions of H.R. 1145 has been developed after consultation with appropriate Federal and non-Federal experts, including staff of the Science and Technology Division, Library of Congress. This analysis included a consideration of the application of state-of-the-art technologies (much of which are still experimental) to..."transcribe and store all biomedical information," as the bill requires, to a collection on the scale of the holdings of the NLM; the costs of translation from foreign languages where necessary; and other requirements of the bill. The preliminary estimates for translation costs alone would suggest a minimum one-time cost of approximately $4.3 billion and additional annual costs estimated at approximately $165 million. Other requirements within the proposal for which costs could be estimated would require an additional one-time figure of $45 million for transcribing and storing all articles full text onto videodiscs, and $40 million annually to maintain the currency of the database and fund the National Center for Research Accountability.

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Question: Do you think this is a feasible proposal?

Answer: The bill is based on the premise that a great deal of redundant research is performed that results in wasteful use of research animals, and that the redundancy occurs because of an inefficient system of storage and dissemination of biomedical information. We disagree with this hypothesis. Deriving from it are the bill's two major requirements: a review process based on examination of the scientific literature to determine the necessity of proposed research, and a system whereby the NLM would make available to medical libraries throughout the country an online computer database with the full text of all current and archived scientific literature. This would be in addition to NLM's current bibliographic computer services and document delivery services, which currently do provide citations for articles, and abstracts for most articles. We believe that the proposed review system is unnecessary, in light of existing scientific review systems throughout the government, and impractical; and that the proposed library system is not needed and would be a massive and costly undertaking. The question of copyright is not mentioned in the bill, but complex legal issues would have to be resolved if copyright material were used in such a fashion.

FUNDING FOR NEW INVESTIGATOR-INITIATED AWARDS

Question: Your ability to fund new investigator-initiated awards is severely compromised under your FY 1986 budget proposal (13 new awards compared to 64 started in FY 1985 and 49 in FY 1984). Please explain the sharp drop in number of new awards.

Answer: NLM initially estimated it would be able to fund 13 new awards under a FY 1986 budget held to the FY 1985 level. However, revised estimates now indicate that approximately 25 new awards will be funded in FY 1986. The Extramural Programs budget for FY 1985 was increased approximately 61% over the FY 1984 budget level. This resulted in an increase in the number of new awards to be made during FY 1985. The vast majority of the new awards are for projects of more than one year. Therefore, the commitment base for noncompeting, renewal awards in FY 1986 will increase, thereby reducing the number of new awards under a level budget.

Question: What areas of research will not be supported?

Answer: Those applicants scoring highest after undergoing scientific merit peer review will receive first consideration for funding. However, NLM's priority areas of interest remain Medical Informatics and IAIMS.

Question: How many awards did the National Library of Medicine ask for in its first budget submission?

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Answer: NLM's first budget submission included an estimate of 75 new awards.

COMPUTERS IN MEDICINE

Question: Can you please comment in general on the burgeoning field of computers in medicine?

Answer: Computers are now almost universally used in hospital management systems in which they control the business and housekeeping activities of the hospital. These include but are not limited to billing, inventory control, patient scheduling, management of controlled substances, and portions of the patient record such as laboratory tests. The computer is rapidly assuming these functions in many office practices as well.

The computer has also made possible the introduction of a large number of extremely valuable non-invasive diagnostic techniques such as the CAT scan, magnetic spin resonance and ultrasound imaging of the body.

Access to the medical literature and now the delivery of medical information in the form of whole text through computer mediated electronic systems is a present day reality.

Computers have also become the indispensable tool of medical research, making possible nucleic acid sequencing of DNA and amino acid sequencing of peptides. They are also indispensaable to the researcher as data recorders and interpreters.

Despite this pervasive use of computers in all aspects of medicine, there remains unsolved the problem of integrating information from all these sources even when each exists as a computer file. Unfortunately there is no present way in which these many files can be brought together into a single synthesized whole or even where one file can search another for relevant information. To accomplish this critical task requires that in some definable way all the information in the various files be structured in an identical manner. To put it simply, all the files must either speak the same language or they must speak a common language. This is especially important in the case of unstandardized terminology used to record patient findings, diagnoses, and treatments into the medical record. The next quantum leap forward in exploiting the computer in medicine is dependent on solving this problem.

The solution will require very considerable resources in money and research manpower as well as cooperation between many organizations both public and private. While it is unlikely that any single organization working alone could accomplish this task, its importance demands that it be undertaken. The National Library of Medicine has set as one

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of its highest priorities the spearheading and coordination of such an effort.

Question: Which medical disciplines lend themselves most readily to computer applications?

Answer: Computer applications are easiest when the input data is reliable and reproducible, when the knowledge domain is narrow and when the patho-physiology of the disease and the pharmacology of appropriate drugs is known. These conditions not only vary from medical discipline to medical discipline but also vary within medical disciplines. At least some aspect of all medical disciplines lend themselves readily to computer applications. Practical and important computer systems exist in clinical laboratory, electrocardiography, surgical and medical intensive care monitoring, oncology cancer treatments, obstetrics, psychiatry and radiology.

Question: What are the prospects that increasing use of computers may help reduce the costs of health care?

Answer: The prospects are excellent. Computer mediated information systems increase the likelihood of earlier diagnosis and institution of the best treatment. The best treatment is always the cheapest treatment because the cost of the initial treatment, no matter how high, is never as great as the cost of treating the sequelae of an initially mismanaged case. In addition, more efficient patient scheduling, more rapid and more reliable interpretation of laboratory results and better treatment monitoring all result in reduced hospital admissions and shorter hospital stays.

PREVENTION RELATED ACTIVITIES

Question: In a speech before the American Pharmaceutical Association, Dr. Wyngaarden said that 28 percent of NIH funds are directed to preventive research. What types of preventive research are being done by your Institute?

Answer: The National Library of Medicine does not perform research on prevention of particular diseases. However, NLM does provide information support for prevention as well as all other biomedical activities by serving as the nation's principal resource for information in support of biomedical research, health professional education, and the delivery of health care services in both the private and the public sectors. Users include commercial and industrial organizations, hospitals and other health care institutions, academic institutions such as medical, dental, and nursing schools, and research organizations.

Scientists believe that a large number of preventable illnesses, including neoplasms, stem from exposure to toxic chemicals and environmental pollution. NLM plays an important part in the national effort to limit and control this danger.

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Services of NLM's Toxicology Information Program (TIP) include online databases such as TOXLINE, CHEMLINE, and the Toxicology Data Bank (TDB). RTECS (Registry of Toxic Effects of Chemical Substances) is an online interactive database built and maintained by the National Institute for Occupational Safety and Health (NIOSH). The TDB contains evaluated data describing the chemical and biological properties, as well as the usage, environmental, and occupational characteristics of selected chemical substances that may be hazardous and/or whose exposure potential is significant.

A major effort of TIP during FY 1984 has been in support of the Department's responsibilities under the Comprehensive Environmental Response, Compensation and Liabilities Act of 1980 (CERCLA), also referred to as the "Superfund Act." The primary objectives are to: (1) enhance the NLM Chemical and Toxicological Files with additional chemical substance records and data pertinent to chemical waste dumps or accidental spills; and (2) improve information dissemination capabilities for officials dealing with hazardous chemicals--often in emergency or remedial situations. These services allow the producers of drugs and chemicals as well as health professionals to have rapid access to information about the effects on humans and the environment of drugs, chemicals, and other toxic substances; they represent a powerful tool for the prevention of chemical disasters as well as disease in individuals.

NLM has arranged with NIOSH to receive a subfile of the NIOSH database containing occupational exposure data not currently in NLM files. This data will be used to enrich TDB and TOXLINE.

NLM is represented on the NIH Disease Prevention Committee. The TIP at NLM has been designated by DHHS as having lead responsibility for the 1990 disease prevention objective which states "By 1990 a central clearinghouse for observation of agent/disease relationships and host susceptibility factors should be fully operational, as well as a national environmental data registry to collect and catalogue information on concentrations of hazardous agents in air, food, and water." In carrying out this responsibility, NLM is a member of a departmental group for Toxic Agents and Radiation Control.

Question: What percent of your budget is directed to preventive research?

Answer: NLM's budget is not formally broken down into this kind of category. On the other hand, the Toxicology Information Program alone constitutes about 6% of the NLM budget. Overall, about half of the NLM budget is devoted directly to providing biomedical information to health professionals.

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Question: How are the results of this research being translated into useful public information?

Answer: NLM resources support prevention research by identifying scientific and technical information (either as a direct user of NLM or through the Regional Medical Library Network) through databases such as MEDLINE and TOXLINE. The results of prevention research must be disseminated to the scientific community if they are to be effectively utilized. Research projects culminate in published results which are acquired, organized, and distributed by the NLM. The Library provides bibliographic references to the literature through printed indexes and online databases.

UNIFIED MEDICAL LANGUAGE

Question: If the correct and most up-to-date information about medical diagnosis and therapy exists in the scientific journals and textbooks that NLM indexes, why is this not used more by physicians in their practices? Answer: There is so much information available now, and progress on new drugs, treatments, and diagnostic procedures is coming so fast that the real problem is to provide the right advice and consultation to the practitioner at the time and place he or she needs it for a particular patient.

Computer systems nowadays are very close to being able to do this kind of thing. They are already available to search legal precedents of cases for lawyers and to search newspapers and wire services and encyclopedias for journalists.

Medicine is falling behind in applying these beneficial systems. This is due both to the difficulty in creating the most appropriate systems specifically for health care problems and because of the absence of training for health professionals in how to use the systems that exist.

Question: What can NLM do to eliminate the problem?

Answer: A major missing capability in medicine is a Unified Medical Language System. Under such a system, the words that are written into the patient record to describe patient complaints, findings, and diagnoses will immediately be linked to the correct information in the published literature and text books. At the moment this cannot happen. The language used to describe and index the literature--Medical Subject Headings--is provided by NLM for worldwide use. It works very well. The language used to describe patient findings and diagnoses is plain English. It is not unified, is not linked to the literature, and does not work well at all.

NLM has begun a feasibility study this year to see if we can take the lead in building a Unified Medical Language System. Our results have convinced us that we can succeed,

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provided that we work with the university research groups, medical professional societies, the AMA, commercial insurance carriers, and use our own experts in the organization of the literature.

ADMINISTRATIVE EFFICIENCY

Question: In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased?

Answer: NLM's relatively small grants and contracts program is efficiently operated and managed by a basic minimal core of analysts and health professional staff.

Question: Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the institute?

Answer: The NLM has a small staff of management and operations research analysts--3.5 FTE--who conduct studies and make recommendations to improve administrative efficiency. These studies typically examine processing procedures and workflow. The improvements which result usually relate to the application of office technology and the more efficient utilization of staff to accomplish increasing service requirements. One dramatic use of technology is the employment of online microcomputers in the indexing of the large volume of literature thereby both speeding the availability of the research results to users and increasing the efficiency of the indexing function.

Question: What changes in procedures have you instituted recently to decrease administrative costs?

Answer: NLM has recently expanded its use of microcomputers in the administrative management of resources. Examples include tracking of obligations and expenditures of appropriated funds, planning and reporting the use of personnel resources, and the tracking of contract and grant processing. These procedures reduce the administrative costs associated with these functions but also result in enhanced management practices at a time of diminished personnel resources.

The current development of NLM's next generation of the Medical Literature Analysis and Retrieval System, MEDLARS III, when completed, will automate, improve, extend and integrate library operations such as ordering, receiving and cataloging the literature. The first phase of these improvements is scheduled for implementation in early FY 1986. These automation initiatives in labor intensive functions help NLM attempt to keep pace with its ever increasing workloads. Such advances will help alleviate the impact of the reduction of some 22 FTE's over the FY 1985 appropriation level.

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The Library is presently completing the development of DOCLINE (Document Location Online), a system for controlling the routing of interlibrary loan requests within the United States Regional Medical Library system. This automated system will provide substantial administrative savings at medical libraries nationwide. In addition, the DOCLINE system will provide management reports on requested material from which NLM can improve its collection policies.

Question: What measures have been developed to help ensure the equitable and complete review of research proposals, despite efforts to decrease administrative costs?

Answer: The important function of peer review of applications for support of research is conducted for the National Library of Medicine by the Biomedical Library Review Committee and the Board of Regents. As we consider this a most important function, every effort will be made to ensure the complete and fair review of all proposals.

Question: What investigations is the Lister Hill Center currently pursuing in the area of optical videodisc technology?

Answer: The Lister Hill Center has several programs which use the optical videodisc as a medium for electronic storage. An example is our use of this technology to help resolve the Library's problem of preserving the content of deteriorating literature. The mass replication capability available for inexpensively reproducing the videodisc also makes it an ideal source for transferring information to the health community. In addition, we are currently using the videodisc and microcomputer to develop and evaluate computer-based education systems for medical education. Recently NLM has discussed a collaborative effort with a private sector firm to explore the digital storage capabilities of the videodisc as a medium to distribute NLM's databases to the biomedical community.

REDUCTION IN FULL-TIME EQUIVALENCY
STAFFING LEVEL

Question: This Committee in the past has recommended position increases for the NLM in order to ensure that basic medical library services will be sustained and research and development opportunities will be exploited. This budget before us calls for a reduction of 22 FTE's. How can you possibly sustain the quality of your services?

Answer: We, of course, will do all in our power to provide effective services to the biomedical community. There probably will be some delays in cataloging and indexing which could slow the availability of the latest published research results to the nation's biomedical community. NLM would focus on the acquisition of only the highest priority of new biomedi-

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cal literature and would alter its cataloging practices to adjust to the reduced resources.

NLM has been able, in the past, to keep pace with steadily increasing workloads through the aid of automated systems and with modest increases in staffing levels, particularly in labor intensive library processing activities.

ADMINISTRATIVE REDUCTIONS

Question: What library services will be reduced in FY 1985 and FY 1986 to comply with these large administrative reductions?

Answer: In FY 1985, the proposed rescission will reduce travel for meetings, conferences, and site visits, decrease printing of indices to the biomedical literature, and reduce the utilization of expert consultants.

The FY 1986 request requires NLM to reduce expenditure levels for some basic library services and to absorb mandatory increases. For example, compared to the FY 1985 Congressional Appropriation, NLM would reduce literature acquisition by more than $450,000, and reduce printing of indices by about $190,000.

Our current cataloging efforts will slow somewhat and implementation of the Library's newly developed preservation program would be deferred.

Questions Submitted by Senator William Proxmire

Question: Dr. Lindberg, on page 348 of your justifications you point out that the Library of Medicine works closely with the Library of Congress and is a regular contributor to their National Authority Cooperative Project. On the other hand you receive assistance from the Library of Congress in cataloging materials in certain languages for which your staff do not have the necessary expertise.

Are these activities handled on a reimbursable basis or are you simply exchanging services in kind?

Answer: The Library of Congress manages and supports the National Authority Cooperation Project and, in fact, generates the vast majority of the name authority records in the database. The name records which NLM and a number of other major research libraries contribute to the project are essentially a by-product of each library's regular cataloging processes. Neither NLM nor the other libraries are reimbursed for these records. Although provision of this data does entail some additional effort, the development of this national authority file benefits all libraries since it reduces the overall volume of costly authority work performed

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at individual institutions and facilitates the sharing of bibliographic information. The National Library of Medicine views participation in this program as one of its national responsibilities.

The Library of Congress provides assistance to NLM in cataloging certain foreign language materials under an interagency agreement between the two organizations. Except for a few hundred titles in Indic and Arabic languages, the Library of Congress has been reimbursed for this service since it is outside of its normal cataloging responsibilities.

SUBJECT HEADINGS

Question: Your justifications also indicate you are engaged in developing a machine-readable mapping of your Medical Subject Headings to equivalent terms in the Library of Congress Subject Heading system, a project that will take three to five years.

How much do you estimate it will cost to complete this project?

Answer: The costs for completing this project can be divided into three parts: 1) intellectual costs associated with analysis and review of the two subject heading lists, determination of the degree of equivalence between terms in each list, and preparation of information and guidelines for the use of the proposed conversion tables; 2) programming costs associated with the development of rules providing for computerized matching of terms wherever possible, preparation of computer listings for review, modification of NLM's subject heading file to incorporate reference to equivalent LC headings, and preparation of photocomposed copy for publication of LC-MeSH conversion tables; and 3) storage and processing costs associated with use of the NLM computer, and printing and publication costs.

The estimated cost for this project is $92,000; most of the cost is for personnel performing the intellectual analysis and review.

TOXICOLOGY INFORMATION PROGRAM

Question: Dr. Lindberg, in your prepared statement you refer to the Toxicology Information Program as your intramural program to provide specialized information services in the areas of toxicology and environmental health.

How does this program interact with the Applied Toxicological Research and Testing program run by the National Institute of Environmental Health Sciences?

Answer: The Toxicology Information Program (TIP) of NLM has developed data files and state-of-the-art mechanisms

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of information search and delivery that are supporting National Institute of Environmental Health Sciences (NIEHS) scientists and science administrators, among others, in carrying out the missions of the NIEHS Applied Toxicology Research and Testing Program.

TIP services allow NIEHS personnel to efficiently identify research that is pertinent to the design and maintenance of new research or toxicologic testing as well as preventing the expenditure of human and fiscal resources on scientific experimentation that would be unnecessarily duplicative.

Through an array of contact mechanisms TIP maintains an in-depth understanding of the ongoing and proposed informational needs of scientists and science administrators not only at the NIEHS but also of individuals with similar backgrounds representing other Federal and State Agencies, industry, and academe. This continual dialogue ensures, that, as far as resources permit, the Toxicology Information Program can maintain and develop information activities that are relevant to the needs of public and private sector scientific communities.

NEW SUBJECT HEADING

Question: I was delighted to learn recently of the Library's plan to create a new subject heading entitled "animal testing alternatives" for use this year in some of its periodicals and databases. Will this be a permanent new heading?

Answer: Yes. As an information service to all who have an interest in this area, NLM now uses the subject heading, "Animal Testing Alternatives," for appropriate articles from journals indexed in Index Medicus beginning in 1985. The scope description for this heading, published in Medical Subject Headings, Annotated Alphabetic List, 1985, includes "procedures, such as tissue culture, mathematical models, etc., when used or advocated for use in place of the use of animals in research or diagnostic laboratories."

Medical Subject Headings (MeSH) is the list of descriptors used by NLM for indexing articles from over 3,000 of the world's leading biomedical journals. MeSH descriptors are words and terms which characterize an article's content. The new subject heading is now available for searches in MEDLINE and other databases indexed with MeSH.

Question: Can you tell us where this new heading will be used?

Answer: The National Library of Medicine (NLM) is now using "Animal Testing Alternatives" as a subject heading in the 1985 editions of its catalogs and computer databases,

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which help users throughout the world find biomedical books, articles and audiovisual materials.

Indexers use this subject heading only for published articles which explicitly state that the test, assay, or method is proposed as a substitute or alternative for procedures using live, intact animals; or if the in vitro procedure is a predominant objective of the publication.

The heading will be used in these NLM periodicals and databases:

1. Index Medicus, a monthly publication that catalogs articles published by more than 3,000 biomedical journals around the world.

2. Current Catalog, a quarterly publication that cites biomedical books, pamphlets and printed materials.

3. Audiovisual Catalog, which lists biomedical films, videotapes and other audiovisual materials.

4. MEDLINE, a computer database comprising citations similar to those contained in Index Medicus. Using a library terminal or personal computer linked to the MEDLINE database, a person may use the new subject heading to create lists of relevant articles quickly.

5. TOXLINE, a bibliographic database with about 1,500,000 references to the toxicological effects of drugs and other chemicals; a portion (circa 15%) of TOXLINE is taken from MEDLINE and carries this heading.

People searching through mountains of scientific literature for the latest information on alternatives to animal testing soon will have an easier time of it. The new heading will make such searches routine and make the results available to a far wider audience.

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OFFICE OF THE DIRECTOR AND BUILDINGS AND FACILITIES

STATEMENT OF CALVIN BALDWIN, ASSOCIATE DIRECTOR FOR ADMINISTRATION

ACCOMPANIED BY:

DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

DR. EDWIN D. BECKER, ASSOCIATE DIRECTOR FOR RESEARCH SERVICES, NATIONAL INSTITUTES OF HEALTH

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. Next, we will hear from the Office of the Director of NIH. This will also include a discussion of the appropriation for buildings and facilities.

The budget request for the Office of the Director is for $35.7 million, and for buildings and facilities $14.9 million.

The principal witness for both these appropriations is Calvin Baldwin, Associate Director for Administration at the National Institutes of Health.

Your submitted statement will be placed in the record at this point.

[The statement follows:]

STATEMENT OF CALVIN BALDWIN

I am pleased to have the opportunity to discuss with the committee the Office of the Director and the buildings and facilities appropriations of the NIH.

OFFICE OF THE DIRECTOR

This appropriation funds those components of the central administration which are primarily responsible for the development of NIH-wide policy and procedures and the coordination of program activities. Chief among these offices is the immediate Office of the Director, including the principal associates of the Director and staff officers who provide advice and assistance in the administration and coordination of the intramural and extramural research programs of the bureaus, institutes, and divisions.

Other offices provide leadership in such areas as equal opportunity, program planning and evaluation, disease prevention, medical applications of research, public and scientific communication, protection from research risks, management analysis and review, contracts and grant administration, and budget and personnel management. These offices are assisted in their efforts by numerous formal and informal advisory groups, both internal and external to the NIH, representing a wide array of viewpoints on issues central to the administration of biomedical research.

Mr. Chairman, the appropriation request for 1986 for the Office of the Director is $35,710,000.

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BUILDINGS AND FACILITIES

The second appropriation about which I am testifying is the buildings and facilities appropriation that provides funds for the design, construction, and repair and improvement of clinical and laboratory buildings and supporting facilities for the National Institutes of Health.

The appropriation request of $14,900,000 in fiscal year 1986 is for the following:

Clinical center modernization.—The clinical center, completed in 1955, houses all the patient care and clinical research programs of the National Institutes of Health at Bethesda, as well as some of the basic research programs. In fiscal year 1986, we are requesting $7,400,000 to continue the modernization of this building. The modernization effort began in 1979 and is required to remove functional obsolescence and repair physical deterioration: to satisfy the latest code requirements for the handicapped, for environmental health, and for the safety of the patients and staff: and to integrate the activities in the clinical center with their operational counterparts in the new ambulatory care research facility. The program, involving more than 50 projects, is scheduled so that clinical and basic research can remain operational during the entire modernization period.

Rehabilitation of laboratory buildings 2, 3, 4, 5, 7, and 8.—We are requesting $2,500,000 in fiscal year 1986 to provide for the completion of the building 4 construction and the design of building 5 as part of the long-term rehabilitation effort. These laboratory buildings, constructed in the 1930's and 1940's, are structurally sound, but the support systems and interior architectural features are inadequate in capacity and/or are badly deteriorated. Also, the renovated buildings will meet the requirements of the handicapped, new life safety code requirements, and energy conservation provisions.

Design funds were appropriated in fiscal year 1981 for building 8, and the design was completed in late 1982. Funds for the initial phase of construction were provided in the 1983 appropriation authority and funds for completion of building 8 were provided in 1984. The rehabilitation of building 8 will permit relocation of occupants now in building 4 as a continuation of the overall modernization program.

Design funds were appropriated in the 1984 appropriation for buiding 4, and construction funds were provided in 1985.

Repairs and improvements.—The Repairs and Improvements Program applies to the physical plants at Bethesda, Poolesville, and Baltimore, MD; Hamilton, MT; Research Triangle Park, NC; Perrine, FL; and other field stations for which NIH is responsible. Program related repairs and improvements are required to accommodate changes in the direction of research efforts. The request of $5,000,000 in fiscal year 1986 will provide for the continuing need to upgrade extensive physical plants and changes related to program needs.

Thank you. I shall be happy to respond to any questions you may have.

BIOGRAPHY OF CALVIN B. BALDWIN, JR.

December 22, 1925. Radford, VA.

Married, three children.

Education.—A.B., University of North Carolina, 1949. University of North Carolina, 1949–51. American University, 1952–53. M.P.A., Harvard University, 1961. The Dartmouth Institute, June 27–July 23, 1982.

Professional history.—1949–50, Research Assistant, Institute of Research in Social Science, Chapel Hill, NC. 1951–53, methods examiner, Federal Security Agency, PHS. 1952–53, civil service intern, Federal Security Agency, PHS. 1953–55 organization and methods examiner, NIH. 1955–57, budget examiner, Office of the Director, NIH. 1957–58, administrative officer, Division of Research Services, NIH. 1958–61, administrative officer, Division of General Medical Sciences, NIH. 1961–62, executive officer, Division of General Medical Sciences, NIH. 1962–63, Assistant Chief, Grants Management Branch, Division of Research Grants, NIH. 1963–70, executive officer, National Institute of Child Health and Human Development, NIH. 1970–80, executive officer, National Cancer Institute, NIH. 1980–present, Associate Director for Administration, NIH.

Military service.—1944–46, U.S. Army—Infantry.

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Honors, awards.—Phi Beta Kappa. W.A. Jump Meritorious Award, 1960. HHS Superior Service Award, 1973.

SUMMARY STATEMENT

Mr. BALDWIN. Thank you, Mr. Chairman.

I would like to introduce Dr. Edwin Becker on my left who is the Associate Director for Research Services. Let me give you a very brief summary of my opening statement.

My testimony covers two appropriations that support all NIH programs. First, the appropriation for the Office of the Director that includes the Director and his staff who assist in the administration and coordination of NIH programs and for administrative support functions such as budget, accounting, and personnel. The appropriation request for 1986 for the Office of the Director is $35,710,000. The second appropriation for which Dr. Becker and I are testifying is buildings and facilities. This appropriation provides funds for the design, construction, repair, and improvement of NIH facilities. Many of NIH's buildings are in need of rehabilitation and modernization. A major item of our request under this appropriation is $7,400,000 to continue the modernization of the clinical center, the building that houses all of the patient care and clinical research programs of the NIH, as well as some of the basic research. That is a very brief summary, Mr. Chairman, we will be glad to answer questions.

INSTITUTE OF MEDICINE STUDY

Senator WEICKER. My first question is directed to Dr. Wyngaarden. When did the last review of the Office of Director occur, and are you planning a review of that office based upon the concerns raised in the Institute of Medicine report?

Dr. WYNGAARDEN. I don't know that we have had a formal review of the Office of the Director. Maybe someone can instruct me on that.

Senator WEICKER. It is my understanding that that report would indicate a strengthening of your office. Are you aware of the report?

Dr. WYNGAARDEN. Oh, yes; well aware of it.

Senator WEICKER. Do you think it might be helpful to have a review of your office?

Dr. WYNGAARDEN. I think the points I made——

Senator WEICKER [interposing]. Let me ask you this, do you give credibility to the report?

Dr. WYNGAARDEN. We think the Institute of Medicine did a very careful study of the issues that they addressed and they made a number of points that we are studying further. We have assigned this to a committee to review point by point and develop options for response. We agree with some of the points made in the report. We have some questions and reservations about others.

Senator WEICKER. Do you think a review would be helpful?

Dr. WYNGAARDEN. The IOM made points in the report about clearer delegation of authority to the Office of the Director. We met with

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members of that committee, and it wasn't really clear in my mind to what they were referring. Unless they can be more specific about that delegation, I am not really quite sure. Also, the report discusses the advantage of having discretionary funds or transfer authority which would clearly strengthen the Office of the Director in dealing with certain fiscal emergencies that might develop.

LABORATORY RENOVATIONS

Senator WEICKER. In fiscal year 1985, Congress provided $10.1 million for renovation of laboratory buildings. This year you are requesting $2.5 million. Are you all finished?

Dr. BECKER. No; the project is not finished. The renovation of the laboratory buildings is a very long project involving six of the older buildings. The first one, building 8, is being renovated now and the occupants of the next building, building 4, will be moved there in the fall when building 8 is completed. The funds that were appropriated last year provided the bulk of the money for the renovation of the next building, building 4, and the $2.5 million we are requesting this year will permit us to complete that project and to provide for the design of the subsequent building, building 5.

You will see requests for this almost every year for a number of years until that whole project is completed.

Senator WEICKER. Why wouldn't we want to go ahead and provide sufficient funding not just for the design but to get on with the next building?

Dr. BECKER. It takes time to schedule the necessary moves. All the buildings are occupied so we cannot proceed with the renovation of building 4 until its occupants can be located into building 8, and so forth, for the following buildings. There would be no reason to provide funds for the construction of building 5 this year, because we will not be able to use them for another year or two.

PERSONNEL SYSTEM FOR SCIENCES

Senator WEICKER. In June 1984, you presented a proposal for a new personnel system for scientists in the Public Health Service in salary comparability to medical school faculty. What happened to that proposal?

Dr. WYNGAARDEN. That proposal has been submitted to the Secretary's Office where it is under review.

NIH TASK FORCE ON NURSING RESEARCH

Senator WEICKER. Has the NIH task force made its report yet and if so, what is the thrust of its study?

Dr. WYNGAARDEN. Yes; the task force did a very thorough job of cataloging those activites in which nurses are involved and made a number of suggestions to improve their involvement. We circulated this report and discussed it. I then returned it to the original committee and asked them to develop an implementation plan for the various projects

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and additional activities that they felt could be expanded. The plan has just been received and has been distributed to the Institute Directors; it will be a major discussion item at our first meeting after the hearings.

NIH CENTENNIAL

Senator WEICKER. I have further questions for response to the record. We have used up considerable time here. One last question, Dr. Wyngaarden, in 1987 the NIH will be 100 years old marking a long history. I am very proud of the achievement of medical science. Have you begun planning for this centennial?

Dr. WYNGAARDEN. Yes; we have appointed a committee. In fact, former NIH Director Donald Fredrickson is chairing the committee and we have been meeting regularly. We are developing plans for a celebration that will include many activities throughout the centennial year. There will be scientific symposia and social events at the NIH. We hope to have a commemorative stamp to celebrate the event, and we are discussing a TV documentary to make the NIH better known throughout the country.

Senator WEICKER. I want to thank all of you, I want to thank you, Dr. Wyngaarden, and thank all the various directors and those who have taken the time to testify. I don't mind telling you the last 3 days have been a refreshing contrast to the past several months in the sense of the subject matter for thought and discussion. I and the staff will be meeting with you on an individual basis through the offices of Dr. Wyngaarden because it is my intention to try and convince the subcommittee, indeed the full Appropriations Committee, of substantial changes from the administration request. I think you have a right, each one of you, to be very proud of what it is you have accomplished.

I think it has been a great credit to yourself, to the Institute and to the Nation and it is an activity, I think, that clearly should be one of our highest priorities in the sense of the national budget.

So, the matter of cutbacks and the matter of freezes is not a given insofar as this committee chairman is concerned. As we devise our own budget, I will be actively seeking your advice. Again I have to repeat, I intend to work through the office of Dr. Wyngaarden, but it is also true so that nobody needs fear any looking over the shoulder by the administration, that the information is being requested by me—by me. I am not asking you to volunteer anything. I am asking for straight answers to my questions. That, of course, is something that is to be expected and I am sure it will occur.

This concludes our testimony for the fiscal year 1986 budget requests for the National Institutes of Health by administration witnesses. We will, of course, be hearing a great deal more about NIH when we hear from our public witnesses during the first 2 weeks of May.

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QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

The questions I referred to earlier will be placed in the record at this point.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

INSTITUTE OF MEDICINE STUDY

Question. When did the last review of the Office of the Director occur?

Answer. The Office of the Director has been reviewed as part of larger studies of the NIH. Various components have been reviewed in connection with reorganizations or transfers of functions. However, there has never been a study specific to the whole Office of the Director.

Question. Are you planning a review of that Office based upon the concerns raised in the Institute of Medicine report?

Answer. A committee has been assigned to review the issues raised in that report, and depending upon their recommendations, a study of the Office of the Director may or may not be necessary.

LABORATORY RENOVATION

Question. In FY 1985, Congress provided $10.1 million for renovation of laboratory buildings. This year you are requesting $2.5 million. Are you all finished? If not, how much more funding will you need to keep the renovation plan on track in FY 1986?

Answer. We are in the process of making renovations to Building 8, the first building to be refurbished under this program. This work should be completed by the end of 1985, and the occupants of Building 4 can then move to Building 8. The funds appropriated last year, $10.13 million, together with the $2.5 million requested for FY 1986, will permit the renovation of Building 4 and design of renovations for Building 5.

Question. How much disruption will occur, if you do not receive this additional funding?

Answer. The $2.5 million requested is critical to maintaining the pace of this project, but funds beyond that could not be effectively used in FY 1986. The next stage, renovation of Building 5, cannot begin until its occupants are relocated to the newly renovated Building 4.

NURSING RESEARCH

Question. Has the NIH task force on nursing research made its report yet?

Answer. The NIH Task Force on Nursing Research released its report in December 1984. The Director, NIH, established the Task Force to assess the extent of NIH support of nursing research; to evaluate the feasibility of increasing NIH support of nursing research consistent with the NIH mission; and to examine the current and potential role of nurses in NIH peer review groups, advisory committees, councils and boards.

Question. What is the thrust of its study?

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Answer. The thrust of its conclusions centered on enhancement of the nursing research environment at NIH. The report's recommendations identified ways in which NIH could strengthen its support of nursing research and training and could increase the number of nurse advisors and reviewers within the existing advisory structure.

Question. What recommendations does it have pertaining to the advisability of establishing a new National Institute of Nursing?

Answer. The Task Force did not deal with the organizational locus for nursing research nor did its recommendations, per se, touch upon establishment of a new National Institute of Nursing. The report merely suggested that there is a clear place for increased support of nursing research activities at NIH consistent with the NIH mission. The NIH opposes the creation of a new National Institute of Nursing. Increased emphasis on nursing research at NIH can best be assured through multi-institute participation in interdisciplinary research and training within the extramural and intramural programs.

CLINICAL CENTER

Question. I note that you are requesting only $7.4 million for modernization of the Clinical Center. How much was appropriated in FY 1985?

Answer. Funds of $6.9 million were appropriated in FY 1985.

Question. Given the concern expressed earlier in these hearings about lack of bed space, are you requesting enough funding to do what has to be done?

Answer. The pace of the Clinical Center modernization project is determined not only by the funds available, but by the amount of disruption to research and patient care activities that can be tolerated and by the necessity of doing the projects in sequence so that programs can be relocated. The $7.4 million requested for FY 1986 should suffice to perform the work that is feasible at this time.

Question. How much more would you need to keep the renovation on track?

Answer. As indicated above, we believe the renovation is proceeding on track at the current budget levels and should be completed by 1993.

PUBLIC HEALTH PERSONNEL

Question. What have you done in the past year to implement the Committee's recommendation that you tap the resources of personnel within the Nation's schools of public health?

Answer. As an integral part of its search for highly qualified individuals to be members of NIH public advisory committees, the NIH encourages its staff to look both to schools of public health and to related components in other institutions

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(e.g., departments of public health, epidemiology, and biostatistics).

A review of the current membership of NIH public advisory committees showed that there are 50 individuals recruited from such sources. These individuals make an invaluable contribution, and the NIH will continue to implement the Committee's recommendation to tap members of this community for their unique expertise and perspective.

Question. Have such individuals been considered for appointment to advisory councils?

Answer. Faculty members from the Nation's schools of public health and related entities have been nominated and appointed to serve on the national advisory councils of the NIH.

Currently, there are 14 members of NIH councils who work in various fields involved with public health. Nominations of such individuals for service on NIH councils will continue to be made by NIH staff as well as interested individuals and organizations within the public.

OFF-CAMPUS SPACE

Question. I understand that you are presently renting 452,000 square feet of space off the NIH campus at $5.4 million per year. Have you developed any plans to effect cost savings on this off-campus space?

Answer. The FY 1985 appropriations act that covers GSA provides authority to contract with a private developer for construction of buildings on Government land and lease of the buildings to the Government at a rate calculated to amortize cost of construction over a period of years. At the end of this period title passes to the Government.

We have recently had an economic analysis carried out by a real estate consultant. The analysis indicates that over a 20-year period the cost of a lease-purchase arrangement for the necessary office space and parking facilities on the campus would be just about the same as the anticipated lease costs plus the additional expenses of maintaining the programs off-campus. However, the on-campus building would become Government property after the 20-year period, whereas lease costs, with adjustments for inflation, would continue each year.

Question. What kind of approval will be necessary to implement these plans?

Answer. NIH is endeavoring to have GSA use its authority for this lease-purchase project. Meanwhile, we are preparing concept designs for the building and taking steps to update our master plan to include such a building.

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BARRIERS TO THE HANDICAPPED

Question. Congress provided $940,000 in 1984 to remove barriers for the handicapped at the NIH campus. What is the status of that project at the moment?

Answer. Several projects are being pursued with the $940,000 appropriated in FY 1984: 1) the design is almost complete for a main entrance and elevator tower for Building 13. This is a four story building, originally constructed for shops and warehouse space, that houses about 567 people but has no passenger elevator and no access for the handicapped; 2) in order to provide an overall strategy for utilizing the funds most effectively, we engaged an architectural-engineering firm that specializes in such work to survey the NIH campus and provide recommendations for eliminating barriers. Their recommendations were further reviewed by the NIH Handicapped Committee, which is composed of employees who either have various types of handicaps or are interested in helping the handicapped. The committee provided a sense of priority for the various projects, and detailed designs are now underway for those of highest priority that can be accommodated within the funds available; and, 3) as part of other projects, such as Clinical Center modernization and renovation of the older laboratory buildings, we are also removing barriers to the handicapped.

CHILD HEALTH RESEARCH FACILITY

Question. The NIH received $500,000 in FY 1985 to update the design of the Child Health Research Facility. What is the status of this project and what is its estimated funding requirement?

Answer. After careful study it has been determined that a redesign of the building is needed to meet current program needs and energy conservation standards. NIH has placed a synopsis in the Commerce Business Daily to start the selection of an architect/engineer and construction manager. An estimated $57 million will be required for the remainder of the design and construction.

BUDGET

Question. How much additional funding would be necessary in FY 1986 to maintain the Office of the Director and Buildings and Facilities at the same level of effort as FY 1985?

Answer. The Office of the Director would need approximately $1,918,000 in FY 1986 to maintain the same level of effort as FY 1985. The request for the Buildings and Facilities is sufficient to maintain the same level of effort initiated in FY 1985.

Question. What is the effect of the rescission, salary absorption and Section 515 deferral on these offices?

Answer. The rescission and absorption of the pay increases will be achieved through across-the-board reductions in areas such as personal services, travel, printing, supplies and equipment and through administrative actions, such as the elimination of the OD summer employment program.

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ASSOCIATE DIRECTOR FOR PROGRAM PLANNING AND EVALUATION

Question. I understand that the resignation of Dr. Michael Goldberg, Associate Director for Program Planning and Evaluation, has generated a study of that function. When will that study be completed and can you tell us anything concerning your future plans for this office?

Answer. The study of the Office of Program Planning and Evaluation has been completed, and the study report is under review. The range of essential staff functions historically performed by this Office, such as planning, legislative analysis, evaluation, and policy analysis, will continue. The policy analysis function will be somewhat restructured to enhance our capability to respond to major issues of science and public policy, while maintaining our strength in all functional areas for which this Office is responsible.

COST EFFICIENCY AND EFFECTIVENESS

Question. Pressures to reduce costs are perhaps greater now than ever before. But opportunities for immediate monetary savings should be closely examined for possible long-term costs which may exceed the immediate savings. One approach to cost savings is through energy conservation. Measures such as reducing outside air filtration rates, insulating, and installing lower energy-demanding lighting can decrease expenditures on energy. But these savings should not be at the expense of the productivity, health, well-being or comfort of the workers in the work place. What measures have been taken by NIH to conserve energy yet ensure healthful indoor air, good lighting, and generally healthful work conditions?

Answer. Recent measures taken by NIH consist of the following:

- Energy recovery, transfer of heat from exhaust air to supply air, has been installed in new or renovated laboratory and animal buildings since the mid-1970's. The recovery devices used preclude any cross-contamination which could endanger health.

- Automatic night and weekend air conditioning system shutdown and/or temperature setbacks are used in some office buildings. Outside air in these buildings has been reduced to the minimum needed for healthful indoor air quality.

- Auxiliary air chemical fume hood systems are used in many laboratory buildings to minimize summer cooling of the high outdoor air quantities required.

- Storm windows and sunscreens have been added to reduce energy use in Building 31.

- Any new or renovated buildings in the last ten years have been computer analyzed to determine optimum energy use, considering such features as wall and glass insulation and energy-efficient equipment and systems.

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- The street lighting system at NIH, approximately 700 lamps, is being converted from 175-watt mercury vapor lamps to 150-watt high pressure sodium lamps by simple lamp replacement. In addition to the 25 watts of electrical energy saved per unit, there is the additional benefit of an approximate 35 percent improvement in lighting since high-pressure sodium lamps are more efficient in converting electrical energy into lumens. The mean lumen output of the 175-watt lamp is 7,200; that of a 150-watt HPS lamp is 10,800.

- Many stairwells, corridors, and mechanical and storage rooms have had the very inefficient incandescent fixtures replaced with fluorescent fixtures. Stairwells and corridors, typically lit with 75-watt lamps, receive equivalent lighting levels using a fixture containing a 13-watt fluorescent lamp. Mechanical rooms and storage areas, typically lit with 100-watt or greater incandescent lamps, function at a somewhat reduced level if replacement is on a one-for-one basis.

All of the above features are automatically considered for any new construction projects. Additionally, NIH is investigating methods of improving efficiency and/or energy conservation in the Power Plant, Buildings 11 and 34. Further extraordinary energy reductions in lab and animal buildings are being investigated, including outside air reduction, relative humidity reduction, chemical fume hood modifications, and other innovative features, always alert to avoid compromising of medical research or personnel health and safety.

Question. Another approach to cost savings is with regard to equipment and space, both of which can be very costly to NIH. How are decisions made at NIH concerning use, acquisition, and disposal of equipment and space? By whom? How are these decisions coordinated across the Federal agencies?

Answer. The acquisition of new equipment is authorized by designated Bureau, Institute and Division (BID) program officials, based on the dollar value of the item being acquired. All property in use is under the control and care of a designated custodian. When BID programs no longer need property charged to their areas the items are transferred to the NIH Property Utilization warehouse where it is displayed for reissuing to other NIH and DHHS programs.

Decisions on the disposition of NIH excess property are coordinated, in most cases, with GSA. After 90 days, if NIH is not successful in reissuing its excess property within its area, it is reported to GSA for disposition instructions. GSA issues excess property bulletins throughout the federal government and frequently NIH excess property is requested by other agencies as a result of that bulletin. If no requests are received for excess property, GSA issues disposal instructions. In FY 1984, the NIH reissued 3,000 items of used equipment, valued at $3,600,000, to NIH areas. That year, the NIH acquired 300 pieces of property, valued at $2,500,000 from other federal agencies through the GSA excess property program bulletins.

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Decisions relative to the allocation and retention of space are made by the Director, NIH, based on demonstrated program need. A space inventory is maintained for each organizational component comprising the NIH. Acquisitions of any form, like, construction and leases for example, are not initiated until that inventory, as a whole, has been thoroughly reviewed to ascertain that the pending requirements cannot be accommodated.

Likewise, decisions pertaining to the disposal of space are based on program need. If, as a result of our ongoing surveillance of space utilization, there is found to be excess space, GSA is notified through an established process. Prior to the release of space to GSA, pertinent information as to space availability is disseminated to other PHS and Department organizations.

FTE REDUCTIONS

Question. What will be the effects on your administrative staff of the reduction in FTE's?

Answer. In order to minimize the adverse impacts of staffing reductions, we will review selective functions, such as the personnel offices for efficiencies, and consider organizational restructuring and pooling of resources.

Question. Are there already areas in which you are understaffed?

Answer. There are no specific areas in which we are understaffed, however, several programs have been delayed or eliminated due to the staffing reductions, such as the summer program, for example.

Question. How will the intramural research program be affected by the reduction?

Answer. A portion of the FTE reductions will come from the intramural research program, however, every effort will be made to minimize the impact of the FTE reduction on the science being conducted at NIH.

Question. Does the restriction of FTE's limit the ways in which you could utilize budget increases in the intramural program?

Answer. With organizational restructuring and realignment of positions, NIH will be able to utilize the budget increases in the intramural program.

ADVISORY COMMITTEE

Question. How are members of your various advisory committees chosen?

Answer. Approximately one-quarter of the membership of each NIH public advisory committee terminates each year. Institute staff review their upcoming vacancies and decide what areas of expertise must be covered when those vacancies occur. New members must be selected carefully in order to maintain an adequate and

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balanced review of biomedical and behavioral research grant applications and contract proposals, and quality advice on the programs of the NIH Institutes.

Selection of members of NIH public advisory committees begins with the executive secretary of each committee. The executive secretary consults with other Institute staff, with current and former committee members, and with appropriate scientists associated with foundations, organizations, and academic institutions. The executive secretaries also use the computerized NIH Consultant File to seek names of individuals who have expressed an interest in participating in peer review activities of the NIH.

A slate of nominees is developed, approved by the Institute Director, and submitted to the official who is authorized to make the final selection and appointment. The President appoints to two NIH committees; the Secretary appoints to 19 NIH committees; and the Director, NIH, by delegation from the Secretary, appoints to 129 NIH committees. The latter committees provide scientific and technical review of research proposals as well as program advice.

Question. What specific efforts do you make to include representatives of minority groups and health professionals such as nurses?

Answer. Since 1978, it has been the policy of the NIH to include at least one female and one minority on each slate of candidates submitted annually. In addition, if unable to nominate a female or a minority candidate, the executive secretary is required to submit a waiver request in writing stating what efforts were expended to secure the services of such a candidate. This request for waiver must be approved by the Deputy Director, NIH.

For other selected health professionals such as nurses, when resumes of these individuals are received from individuals or organizations, they are circulated to all Institute Directors for their consideration as vacancies occur. Executive secretaries are encouraged to include these health professionals on their committees as the need arises. In the computerized NIH Consultant File, individuals can be located by type of education, degree, or area of expertise; therefore, these individuals may also be located through that resource.

Question. How effectively do the Institutes use their advisory committees?

Answer. The NIH Institutes depend heavily on their public advisory committees. Section 475 of the Public Health Service Act mandates peer review of research grant applications. This mandate is implemented through NIH public advisory committees. Of the currently existing 150 NIH public advisory committees, 114 are devoted to initial scientific peer review of applications, proposals, and projects. The 14 NIH councils and boards review the programs and make final recommendations to each Institute Director on the merits of funding the applications, proposals, and projects approved by the initial review groups. These

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recommendations are implemented by the Institute Directors. The remaining 32 committees provide valuable advice and recommendations on NIH policy, intramural science, and special programs, advice sought and used extensively by the Director, NIH, and the Institute Directors.

Question. Does the use of advisory committees vary among the Institutes? Why?

Answer. The basic use of NIH public advisory committees among the Institutes is the same, i.e., to benefit from the advice of outside consultants in the review of research grant applications and contract proposals, as mandated by Section 475 of the PHS Act; for advice on the conduct on intramural research; for recommendations on the various scientific programs administered by the Institutes. In addition, all NIH public advisory committees are managed consistently in accordance with provisions of the Federal Advisory Committee Act and Department policies and procedures. Variations in the use of NIH committees occur primarily because of the different substantive areas of research addressed by each Institute, and because of the differences in the group dynamics within individual committees.

INFORMATION DISSEMINATION

Question. Please describe the activities of your Office of Communications and the public affairs offices of the Bureaus, Institutes, and Divisions in disseminating information about NIH research results to the health community and the public.

Answer. The NIH's Office of Communications and the Public Affairs Offices of the constituent Bureau, Institutes, and Divisions are responsible for the preparation and distribution of informational materials regarding the results of research conducted or supported by the NIH. For example, our current catalog lists 750 publications and each year the Agency produces about 80 new pamphlets, brochures or larger publications for the use of scientists, health professionals or the general public. Last year, the cost of preparation and distribution of such publications was about $8.5 million dollars.

More than half of the publications developed and published by the NIH are scientific and technical reports, monographs, scientific conference proceedings, bibliographies, and similar materials.

Nearly 30 percent of NIH publications are brochures, booklets and fact sheets on specific health problems prepared for the layman; these are used mostly for responding to the approximately 900,000 public inquiries we currently receive annually.

In addition, the NIH Public Affairs Offices produce a weekly radio interview program, which is distributed in various formats to 200-250 radio stations, and produce and distribute occasional videotape programs as well as a limited number of public service announcements.

Question. To what extent have moratoria or restrictions on publishing hampered your technology transfer activities?

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Answer. The moratorium on publications and the subsequent restrictions have required us to reduce the number of new publications produced each year. We have given priority to the publications most directly involved in technology transfer to the scientific and professional communities, and, thus, have avoided significant curtailment of that function.

RESEARCH COORDINATION

Question. What mechanisms do you have for coordinating research that involves many Institutes?

Answer. The NIH uses a number of mechanisms to coordinate funding and other activities affecting research relevant to more than one Institute. The most common of these mechanisms is the Trans-NIH coordinating committee, which is composed of representatives from all Institutes with responsibilities impinging on a given subject. Examples of Trans-NIH programs with coordinating committees are the Trans-NIH Diabetes Research Program, the Trans-NIH Arthritis and Related Muscular Diseases Research Program, the Trans-NIH Digestive Diseases Research Program, and the Trans-NIH Biomedical and Behavioral Nutrition Research and Research Training Program. In some instances, this extends to Trans-PHS initiatives as in the case of AIDS.

A less formal but equally effective mechanism is the establishment of a lead Institute together with the designation of an individual in that Institute who is responsible for coordinating information on the ongoing activities and plans throughout the NIH. For example, the National Institute of Environmental Health Sciences plays this role with respect to toxicity testing and the development of testing methods.

Scientific conferences and seminars are supported by, or held at, the NIH on topics that are of importance to more than one Institute. The intramural staff and the extramural community funded by the involved Institutes are invited to attend.

Individual initiatives of the Institutes in areas that might overlap are generally implemented through the extramural research community via requests for grant applications or contract proposals. These requests are reviewed within the Office of Extramural Research and Training and coordinated with all concerned prior to publication.

ADMINISTRATIVE EFFICIENCY

Question. In what ways can the administrative costs associated with grants, interagency agreements, and requests for proposals be decreased? Do you have an ongoing program to study and recommend ways to improve administrative efficiency at the Institute?

Answer. NIH has a number of staff offices and internal advisory committees which study and recommend ways to decrease costs by improving administrative efficiency. The major approaches of these groups are directed toward:

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A. Implementation of the use of emerging electronic technologies. A number of these approaches have been or shortly will be implemented. Others under evaluation are:

- The Telecommunications Steering Committee's evaluation of the establishment of a NIH-wide Local Area Network (LAN) to link existing and future LANs. Enhanced electronic communication, coupled with advances in printing equipment, will some day eliminate physical transfer of paper in the extramural review and awarding process. The OMB draft Circular on Management of Information Resources encourages the use of new technology for the collection and dissemination of information.

- The Division of Computer Resources and Technology has established a program for the purpose of advising and training in the use of personal computers.

B. Optimum allocation of resources.

- The Office of Administration has been conducting a study, for some time, for the purpose of gathering data on current use of staff resources. That Office shares these data periodically with various NIH internal advisory and oversight groups.

- A Resource Allocation Group at NIH meets regularly for the purpose of examining present resource allocation and advising the Director, NIH, regarding optimum use of all available resources, particularly personnel slots, space, travel ceiling, and consultant services ceiling.

C. Elimination of administrative burdens, when possible, and implementation of more efficient procedures.

- NIH staff, in collaboration with other staff of the Public Health Service, is examining what kinds of additional authorities might be delegated to grantee institutions under the existing Institutional Prior Approval System. The aim is to improve efficiency and reduce costs, for both the Government and the institutions.

D. Staff training for the purpose of optimizing job performance.

- A senior internal advisory body at NIH, the Extramural Program Management Committee (EPMC), established some time ago a Training Subcommittee. This Subcommittee reviews all existing training programs for NIH extramural staff and, in particular, recommends approaches for new or different activities which will train new scientist-administrators and assist present ones in becoming more efficient in the performance of their tasks.

- The Division of Contracts and Grants has established a certification program for all contracting officers. Training courses are designed for certification at four

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different levels. Completion of prescribed courses prior to certification will ensure improvement in productivity and efficiency.

E. Oversight evaluation for the purpose of identifying strengths and weaknesses in the administrative process.

A number of standing committees at NIH serve the purpose of oversight at it concerns improvement of administrative efficiency. Those dealing solely or partically with extramural matters are:

- The Bureau, Institute and Division Directors, under the chairmanship of the Director, NIH, which advises the Director on all NIH matters;
- The Extramural Program Management Committee (EPMC), which coordinates, advises on and oversees all policy and procedural matter affecting NIH extramural programs;
- The Executive Officers Committee, which deals with administrative issues;
- The Research Contracting Committee, which is concerned with the extramural procurement activities;
- The Review Policy Committee, which concerns itself with issues related to the review of grants, cooperative agreements and contracts.
- The Resource Allocation Group (discussed above).
- The Scientific Directors Committee, a standing committee dealing solely with intramural NIH.

Another committee established recently to deal with more efficient administration is:

- The Productivity Committee, concerned with improving productivity and efficiency throughout the NIH. The EPMC serves as a users subcommittee to the Productivity Committee in extramural matters, i.e., the EPMC provides commentary and critique regarding the operations of the NIH Division of Research Grants.

Question. What changes in procedures have you instituted recently to decrease administrative costs?

Answer. NIH has introduced recently a number of changes to decrease administrative costs, including:

A. Implementing the use of emerging electronic technologies:

- The Division of Research Grants has implemented procedures to reduce the administrative costs in the receipt, assignment, and review of applications requesting research grant support, and the processing of those applications recommended for awards. Examples of these new procedures already implemented are: the

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automating of the assignment process of grant applications, automation of the several steps in the review of applications including the preparation of summary sheets (pink sheets), preparation of books for Advisory Council members, and the computer preparation of award statements.

- The Division of Grants and Contracts is in the process of implementing the computerized preparation of all requests for proposals and of contract documents.

- All PHS agencies are now able to access immediately basic data related to ongoing projects and to applications in process by utilizing terminals compatible with the WYLBUR computer system.

- For several years, the EPMC has been utilizing electronic mail for the purpose of providing agendas and minutes of meetings. In frequent cases, brief summaries of informational material on agenda topics also are available through this same system.

- In order to facilitate communication among the Scientific Directors, the Office of Intramural Affairs has recently installed two computer terminals which permit rapid dissemination to and receipt of information from Scientific Directors' offices.

- Also a program was constructed to allow computerized indexing and searching of Scientific Directors minutes that contain major policy decisions with regard to the intramural programs of the NIH.

- Improvement in administrative efficiency is considered when new policy decisions are made by the Board of Scientific Directors. In recent consideration of policy development with regard to payment of shipping costs for selected service fellows, the importance of reducing administrative workload and, thus, cutting administrative costs was considered in the decision-making process.

B. Optimum allocation of resources:

- Utilizing data from studies and processes described above, all NIH units are able to compare the efficiency and cost of their programs in comparison with others in order to determine if they should either implement major organizational changes or adopt minor procedural adjustments.

- Both the Productivity Committee and the Resource Allocation Group have reported findings and recommendations to various NIH officials and internal advisory groups. This process has resulted in a more equitable allocation of resources, in an information-sharing process designed to improve efficiency and reduce costs, and in a consideration of new approaches and technologies which, when ready for adoption, may provide even more savings.

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C. Elimination of administrative burdens, when possible, and implementation of more efficient procedures.

- NIH has implemented a number of changes which relieves NIH staff from many routine processes, and cuts down the paper flow between the NIH and the grantee institutions. NIH expects to accelerate this trend as it adopts new technologies.

- Implementation of more efficient procedures includes shortening the time and administrative burden to review and award fellowship applications and the evaluation of more equitable, sound and efficient procedures for receipt, review and award of Small Business Innovation Research projects.

D. Staff training for the purpose of optimizing job performance.

- With the approval of the EPMC, NIH has recently implemented a number of approaches to coordinating the training of NIH extramural staff.

Question. What measures have been developed to help ensure the equitable and complete review of research proposals despite efforts to decrease administrative costs?

Answer. In addition to the oversight role of the BID Directors and their Advisory Councils in monitoring the entire extramural program, the Extramural Program Management Committee (EPMC) monitors closely the review process to promote equitable and complete review of all applications. This Committee also makes recommendations, based on studies conducted, to the Director, NIH, regarding the resolution of problems associated with review of applications or ways of improving or making more efficient the review of applications. A recent meeting of the Advisory Committee to the Director, NIH, composed of outside advisors, discussed the review of grant applications at the NIH. The Committee identified concerns of the applicant community regarding the fair and equitable review of grant applications. It identified problems, suggested resolutions and proposed other ways of improving the system. These are currently under study by senior NIH staff.

The Review Policy Committee, coordinated closely with EPMC, studies specific issues related to the review of grants, contracts and cooperative agreements and reports findings and recommendations to the Deputy Director for Extramural Research and Training and to the Research Contracting Committee.

The Research Contracting Committee considers issues related to the review of contracts and the chairman of that committee meets regularly with EPMC and with DDERT to resolve problems and to make recommendations.

Groups which review Small Business Innovation Research Applications include scientists from small businesses for the purpose of bringing to the discussion the perspective of a small, for-profit research organization as compared to that of an academic institution.

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NIH developed an appeals review of applications for grants, cooperative agreements, and assistance awards. By establishing this process, NIH aims to assure the applicant community that every disputed review will be thoroughly examined and, if significant flaws in substance and/or process are found, appropriate steps will be taken to resolve the matter.

Using the appeals process, applicants may request an examination of their concerns relating to the referral and peer review of their applications. Such concerns may involve NIH's refusal to accept an application; a disputed assignment of the application to an initial review group or to an NIH Bureau, Institute, or Division; perceived insufficient expertise on the initial review group or site visit team or conflict of interest on the part of one or more of its members; apparent factual or scientific errors, oversights, or bias associated with the review of an application at the initial or advisory council review; and possibly inappropriate handling of the review or of the application.

Under the appeals process, all concerns must first be directed to the NIH component which at the time is responsible for the application. Appropriate officials will thoroughly examine the investigator's concerns, frequently with the help of the initial reviewers or other experts, and, if shortcomings are found to have occurred, every effort will be made to rectify them in a timely manner.

If the principal investigator seriously disagrees with the response to his/her concerns by the cognizant NIH component, the investigator and applicant organization may jointly appeal to the Office of Extramural Research and Training, which is a component of the Office of the Director, NIH. There the appeal will be examined independently, frequently in consultation with scientific or other experts, and the final NIH decision on the appeal will be rendered by the NIH Deputy Director for Extramural Research and Training and the Institute Director in charge of the application.

Question Submitted by Senator William Proxmire

BUILDINGS AND FACILITIES

Question. Mr. Baldwin, at the end of fiscal year 1983 you had an unobligated balance of $14,565,000 in your buildings and facilities account. Last year, you estimated there would be no unobligated balance at the end of fiscal year 1984 but as we both know it is unrealistic to think you can obligate every penny in a construction account. In point of fact your unobligated balance at the end of 1984 was $14,024,000 again this year, you estimate there will be no unobligated balance of the end of 1985. But realistically speaking, how much do you think you'll be carrying over into 1986?

Answer. It is projected that the unobligated balance in the buildings and facilities account at the end of 1985 will be $12,443,000, most of which ($10.13 million) is allocated to the renovation of Building 4. The contract for Building 4 will be advertised this year but will not be awarded until FY 1986.

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SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will now stand in recess until next Tuesday, March 26 when we will meet at 9:30 a.m. in SD–116 to hear testimony from the Department of Health and Human Services, as follows: Centers for Disease Control; Alcohol, Drug Abuse, and Mental Health Administration; Office of Inspector General; and Office for Civil Rights.

And to end this hearing on the proper note, I now leave the committee room to go down to the gym and do my aerobics. [Laughter.]

Dr. WYNGAARDEN. Let me express my thanks and that of my colleagues for your strong support and for the pleasure of this hearing. We appreciate it very much.

Senator WEICKER. Thank you.

[Whereupon, at 12:18 p.m., Wednesday, March 21, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, March 26.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

TUESDAY, MARCH 26, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:35 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Domenici, Proxmire, Byrd, and Inouye.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE INSPECTOR GENERAL

STATEMENT OF RICHARD P. KUSSEROW, INSPECTOR GENERAL

ACCOMPANIED BY:
BRYAN B. MITCHELL, DEPUTY INSPECTOR GENERAL
DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY FOR BUDGET
JOHN T. HOPKINS, DIRECTOR, DIVISION OF BUDGET SERVICES, OFFICE OF THE SECRETARY

OPENING STATEMENT

Senator WEICKER. The hearing will come to order.

Mr. Kusserow, the Inspector General, will present fiscal year 1986 appropriation request for that office.

The reason why I am going out of turn is that I have to Chair the authorization bill for the Small Business Administration at 11 o'clock when somebody will replace me in the Chair, and I have a few questions that are rather key to this office, and I wanted to make sure that we covered them.

In any event, Mr. Kusserow, you go ahead and proceed with your testimony, and introduce your colleagues.

Mr. KUSSEROW. Thank you, Mr. Chairman.

With me today is Bryan Mitchell, the Deputy Inspector General for our office. We are pleased to appear before you to present our fiscal year 1986 budget request. With your permission, in view of the fact

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that you do have time constraints, if I could summarize my testimony, and then submit the full testimony in a prepared form for the record.

Senator WEICKER. Fine.

Mr. KUSSEROW. In the last 4 years that I have reported before you for our budget appropriation process, we have made substantial improvements in the Office of Inspector General. Our criminal convictions rose from 166 in 1981 to over 900 last year, which is a 442-percent increase; fines, savings, recoveries, restitutions, and settlements rose annually from $165 million to $3.75 billion, which is more than a 2,000-percent increase. Successful sanctions against health providers making false or abusive claims against our programs or against the beneficiaries of our programs rose from 39 in 1981 to 327 in 1984, an increase of more than 700 percent.

Since Secretary Heckler consolidated the sanction authorities for the health care programs of the Department in the Office of Inspector General a little over 2 years ago, we have kicked out 647 providers for fraud or abuse to our programs or beneficiaries, which is more than twice the level of the previous 11 years combined.

All of these accomplishments came about without any budgetary enhancements to my office. I have not asked for any budgetary or staff enhancements in the three previous times that I have appeared before this committee. I am similarly not requesting any increases this time.

For the fiscal year 1986, we will continue to focus our resources on major departmental programs. We will build on past accomplishments by further increasing the inspector general operating efficiency. To achieve this, we are going to reduce the time spent on areas of lower vulnerability or payback and focus our limited resources on the high payback areas of our Department, those areas which are more vulnerable to fraud, waste, and abuse.

We produce investigative audit and inspection reports, oftentimes using a combination of various resources against a single targeted area. We sometimes pool our skills, assigning inspectors, investigators, and auditors to work together on a problem, to create a task force using the appropriate resources.

As I pointed out, we will focus our resources on the larger and more vulnerable programs, most particularly Social Security, Medicare, and Medicaid. We will also allocate the resources needed to address problems identified in the Public Health Service and Human Development Services.

Due to the financial magnitude of Social Security Administration and the health care financing programs, and their persistent costly operational problems, we will focus most of our resources on those areas.

We will continue to review the Department's regulation and legislative proposals, and develop our own cost-effective proposals for legislation. During the fiscal year 1984, we reviewed over 150 major legislative proposals and over 100 significant regulations to ensure that the Department was not creating more problems in the future than it is trying to solve. We wanted to give our perspective at the front-end so that decisions could be made on that basis.

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In closing, Mr. Chairman, let us assure you that our office is making every effort to provide a comprehensive and systematic program for rooting out fraud, waste and abuse in the Department of Health and Human Services. We are also working to ensure that those individuals most dependent upon our programs will receive their full share of benefits available under those programs.

We have only discussed a few of our initiatives. I stand ready at this time to answer any questions you may have concerning our operations.

PREPARED STATEMENT

Senator WEICKER. Thank you very much. Your statement in its entirety will be placed in the record.

[The statement follows:]

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STATEMENT OF RICHARD P. KUSSEROW

I am pleased to appear before you to present the FY 1986 appropriation request for the Office of the Inspector General.

For FY 1986, our budget proposed $70,143,000 in obligational authority of which $40,100,000 is in appropriated funds and $30,000,000 is proposed for transfer in transfers from the social security and medicare trust funds. The $10 million increase in reimbursements from the social security and medicare trust funds is proposed in order to more accurately reflect OIG increased efforts in these programs financed by these trust funds. The $70,143,000 request represents a $2,752,000 savings from the comparable level proposed for FY 1985. The FY 1986 budget request includes the five percent pay reduction proposed by the administration. Finally, the request includes completing the funding transfer of the State Medicaid Fraud Control Unit grants to the Health Care Financing Administrations. Even though actual funding for these units are undertaken with funds appropriated to the Health Care Financing Administration (HCFA), OIG staff and administrative funds will continue to provide the same level of ovesight, certification or recertification of these units as in previous years which is consistent with section 1903 of the Social Security Act.

Since 1981, the Office of Inspector General has actively sought to fulfill its statutory mission of promoting economy and efficiency and preventing fraud and abuse in the Department's programs. To meet this goal, we have redirected our emphasis in line with the allocations of the total budgetary outlays of the Department. Consequently, a majority of our resources are devoted to detecting fraud and mismanagement in programs with high vulnerability such as Social Security, Medicare, and Medicaid. As a result, in the last 4 years that i have reported to you as Inspector General, we have made substantial improvements in these areas. Criminal convictions rose from 166 in 1981 to 900 last year (442% increase). Fines, savings, recoveries, restitutions and settlements rose annually from $165 million to $3,750,000,000 (over 2000% increase). Successful sanctions against health providers making false or abusive claims rose from 39 to 327 (over 700% increase).

In FY 1984, we continued to improve OIG management by increasing our efficiency and effectiveness without additional staff resources. In that year alone, we realized over $3.7 billion in settlements, fines, restitutions, recoveries and savings for all Departmental programs as a result of both management and Congress action upon OIG recommendations. This represents a 166 percent increase over fiscal year 1983.

The realignment of OIG resources to better correspond with Departmental outlays has resulted in substatntial achievements in our investigative and inspections work. For FY 1984, OIG staff produced over 900 successful prosecutions of persons attempting to defraud Departmental programs; an 11 percent increase over the prior year. In addition, State Medicaid Fraud Control Units realized over 400 successful prosecutions at the State level.

In 1983, as part of our effort to further crack down on

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wrongdoers in our health care programs, Secretary Heckler consolidated all of the sanctioning authorities of the Department with the OIG. Since that time, we have successfully "kicked out" over 647 health care providers for cause from the medicare and medicaid programs; 327 in FY 1984 alone. This represents more than twice the total number of such sanctions in the previous 11 years combined. In FY 1984, our first full year of operation, our civil money penalties program collected nearly $8 million in settlements. We expect to far surpass that accomplishment this year. Again, I point out that these results were achieved by improving OIG management and targeting efforts.

For fiscal year 1986, we will continue to focus our resources on major Departmental programs. Our approach is to build upon our accomplishments of the past by increasing further OIG operating efficiency. To achieve this we plan to: reduce time spent upon areas of lower vulnerability and payback; increase our targeting efforts to be sure that limited resources are used where needed; and develop and implement new, innovative, high pay-off techniques for auditing, investigating and inspecting departmental programs.

To accomplish our objective, we produce investigative, audit and inspection reports oft times using more than one approach on the same target. Resources are allocated internally based upon the appropriate response to given problems and situations. The workload is focused mainly on the larger, more vulnerable programs of the Department — Social Security, Medicare, Medicaid, Public Health and Human Development Services.

Due to the enormous magnitude of the Social Security Administration and health care financing programs and their persistent, costly operational problems, the Office of Inspector General will continue to commit most of its resources to them.

In the past, OIG reviews have focused on areas of program and financial management. We have recommended numerous procedural financial adjustments to SSA in significant savings into the foreseeable future. OIG audit and inspection reports had approximately $1.5 billions in savings for FY 1984. We expect that this will improve in FY 1985. In addition, investigations of crimes against SSA in FY 1984 produced 396 convictions and more than 20 million in financial recoveries and savings.

For the coming fiscal year, we plan to increase our use of computer assisted techniques in our auditing and investigative work. We also plan to broaden and intensify our initiatives in Title II and other cross-program areas. The increased use of computer techniques has resulted in the identification of thousands of cases where individuals fraudulently received or were erroneously paid millions of dollars that they should have never gotten. In addition, prevention and detection of employee fraud in SSA programs will continue to be a high priority. Improvements in computer fraud detection techniques are making it possible to take one known case and screen for others. Finally, efforts to reduce the vulnerability to fraud and abuse of the management systems in the SSI program will continue as part of our overall approach to eliminating operational problems and improving management efficiency in ssa programs.

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The Health Care Financing Administration represents the second largest portion of the Department's budget. In keeping with our overall management strategy of matching significant OIG resources against Department vulnerabilities, focus on health care matters represents an equally important priority of this office. During FY 1984, we identified program changes that are resulting in over $1.5 billion in fines, savings, restitutions for the Department. In addition, combined investigative efforts of OIG and State Medicaid Fraud Control Units led to more than 450 successful prosecutions and 372 sanctions against those attempting to defraud or otherwise abuse HHS health care programs. We expect to improve significantly on those results for this year as well as FY 1986.

Emphasis will be on detecting and preventing Medicaid and Medicare provider fraud and abuse; promoting opportunities to avoid additional costs through tightened fiscal controls; and promoting effective management of programs.

For the coming year, we will be devoting extensive resources to evaluating the prospective payment system and the fiscal soundness of the hospital insurance trust fund. We will continue to improve the accomplishments of our sanctioning programs. With the enactment of recently introduced legislation, this job will become even more effective.

For those programs falling under other Departmental offices such as Health or Human Development Services, we will continue to make a high priority the identification of cost savings through consolidation of overlapping activities, productivity improvements, tighter control over cash disbursements and collections, and other changes in processes and systems designed to improve management efficiency and ensure financial integrity. During the past fiscal year, the major directions of our grants and internal systems effort have been in: (1) reviewing Department-wide systems such as debt collection and cash management; (2) improving security at the Department's automated data processing facilities; and (3) insuring the adequacy of the Department's internal controls. This emphasis will be continued and expanded during the coming year. In addition, our audit staff will be taking on new responsibility as part of the implementation of the recently passed single audit act.

We will continue to review Departmental regulations and legislative proposals and develop new cost effective proposals for legislation. During the 1984 fiscal year, we reviewed over 150 major legislative proposals and over 100 significant regulations. We expect this process to expand during the next year.

In closing, Mr. Chairman, let me assure you that this office is making every effort to provide a comprehensive and systematic program for rooting out fraud, waste and abuse in the Department's programs while simultaneously working to provide those persons most dependent upon these programs their full share. I have described only a small part of our activities and operations. More importantly, I have tried in these few paragraphs to show that your faith and trust is well placed with this office. As I stated last year, I believe that our achievement to date reflects the expectations of the members of this committee.

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Senator WEICKER. Mr. Kusserow, I understand that your office has recommended withholding approximately $34 million in Federal Medicaid funds from seven States for training services provided to residents in intermediate care facilities for the mentally retarded, ICFMR's.

You further estimate that up to $585 million could be saved over the next 5 years if these funds continue to be withheld in other States.

Why are these funds being withheld which I understand are used for such required activities as toilet training and self-feeding skills?

Mr. KUSSEROW. Certainly. I want to give you a full statement for the record, but let me say this. I was married for 12 years to a social worker who worked with the developmentally disabled and adult retarded. I have a very strong personal commitment to helping the retarded based on first-hand experience.

Our audits are focused on the administrative costs in these facilities. These dollars could be better spent in the delivery of services. Some facilities have educational training plans set up for people who obviously cannot meet these goals. Sometimes these plans are established to meet the requirements of the statute, without considering whether the plans would enhance the individual's ability to perform at a higher level.

We are trying to focus on the actual delivery of positive services to this particular population, and we want to see this done in a cost-effective manner.

Mr. Chairman, I would like, with your permission, to also submit to the subcommittee copies of our audit reports on ICF/MR, as well as answering more specific questions about this area.

Senator WEICKER. When a State furnishes ICF/MR residents with active treatment services as required by Federal law, they are being told that such expenditures will be treated as nonallowable costs. On the other hand, should the State fail to provide such services, ICF/MR facilities will be decertified for failure to comply with the statute and minimum Federal standards.

As I understand the law, it states that each resident must be trained to be as independent as possible in health, hygiene, and grooming practices, including bathing, brushing teeth, shampooing, combing and brushing hair, shaving, caring for toenails, and fingernails. Each resident who does not eliminate appropriately and independently must be in a regular, systematic training program, and a record must be kept of his progress in the program.

It seems to me, obviously, that education is a part of this process.

Mr. KUSSEROW. Mr. Chairman, that there are some people who may be retarded beyond the ability to train. Some people, despite 50 or 60 years of constant training and having a training plan for toilet training or for grooming, they will never get to the point where they will be able to care for themselves. They will not be able to rise from a diaper situation.

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We are trying to focus on the basic issue of what is the best expenditure on behalf of those developmentally disabled individuals, and whether it is improving their ability to function.

MAINSTREAMING OF THE HANDICAPPED

Senator WEICKER. I have to disagree rather sharply with your first premise there as to the 50 or 60 years and what a retarded individual can or can't do. I might add, I don't do so in any manner of superiority because I am the first one to admit that when I came to the chairmanship of the Subcommittee on the Handicapped, I didn't know what it is that retarded people could or could not do, being very much in favor, when I took the chairmanship of that committee, of institutionalized care as opposed to the mainstreaming concept.

I said at that time, you know there are obviously certain types of persons that can't possibly be mainstreamed, and then I had my first hearing up in Hartford, CT. Believe me, the community as a whole, the physically and mentally handicapped, and all the rest came forth and showed exactly what could be done.

I think that it is safe to say that one of the great tragedies today is the fact that you have the parents of Downs children, let's use that as an example, who today would be above 20 years of age and older, obviously, they, on the one hand, want institutionalized care for their children because the state-of-the-art never permitted their children to progress much, whereas the children born today go through an entirely different curriculum, and indeed they never see the inside of an institution. They will be mainstreamed because of the state-of-the-art of today.

The one thing I have come to learn is that there is no point in saying that so-and-so can't do this or can't do that' The state-of-the-art changes continually, and what we used to think was impossible of being accomplished is being accomplished. It is amazing, absolutely amazing. That is the purpose of the law, as I read the law, and not to go ahead and say that, in effect, you do certain basic things and that is it. Education has been found to be the key and that process of education changes.

You should know that this caused an uproar among the various States because in effect what you are trying to have them do is only restrict themselves to the very basics without understanding the entire education process that surrounds the accomplishment of those basics and other things.

HEARINGS ON CARE OF MENTALLY HANDICAPPED

I might add, if the Nation is not aware of what is going on in terms of the care of our ill and retarded, believe me by the time the middle of next week is over with, they will. We will be having 3 days of hearings, testimony from inmates, attendants, doctors, parents, et cetera, and for the first time the United States is going to see itself, it is going to meet itself on this issue, and it is not going to be a very pleasant encounter, I can assure you, for all of us, whether we are senators, or whether we are the average guy on the street.

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The laws are great. The laws were devised with a great deal of experience and professionalism in hand, but we are not living up to those laws, we truly are not. When the inspector general of the Department comes along and withholds these kinds of funds, it is just devastating insofar as the patients are concerned.

Mr. KUSSEROW. Mr. Chairman, I couldn't agree with you more. I have worked in these facilities. I have worked in community centers for the developmentally disabled and for the adult retarded. I have worked in areas where we are trying to enable these people to move into an independent living facility where they can become a taxpayer. I have seen the miracles of what can be done with them.

Our observations, and that is why I would like to give you the full details of the reports, are that the programs themselves are not doing what we want them to do, or what you want them to do.

Our auditors are not substituting their judgment for the people who are working with this population, but we want to be sure that they categorize the services properly. When facilities claim they are providing services, they have to do it according to what Federal law dictates. We are finding that they are not properly categorizing what they are doing and, therefore, giving us an improper picture.

If they are not providing the services that must be provided for by law, then we think there should be a disallowance. We certainly are not going to substitute our judgment for that of the Congress or the program people, but we as auditors are going to follow the intent of the Congress, and the law and regulations that have implemented these programs.

We have reports to show that facilities are miscategorizing what they are providing, which gives an improper picture. The answer to the broader problem of helping these people is exactly what you said. You have to look at the individual in totality and what kind of services that individual needs to be able to progress to a more independent living capability.

Senator WEICKER. These matters, obviously, are important to all of us. It is my understanding that Mr. George Zitney, who is the Massachusetts Mental Retardation Commissioner, is here at the hearing. His State is one of the seven that you have audited, and apparently there was some disagreement on the issue. After you are through with your testimony, I think the committee will listen to Mr. Zitney for a few minutes, and while you are here in the room, you might want to listen.

Mr. KUSSEROW. I will be delighted.

Senator WEICKER. I might add, I am not going to prejudge this thing. This matter was brought to my attention by the staff just before walking into this room, and I am anxious to have your response in the record.

I will tell you one thing and I want to make it clear. Your background, Mr. Kusserow, is such that I believe in your announced commitment to the ends that are set forth in the law. I am telling you another thing. It might be your personal commitment, but I find the

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Almighty God of this administration and the Department of Health and Human Services is how to save a buck. We are not going to save any bucks at the expense of the retarded and the mentally ill. I want to make that point very clear also.

This is not something that I want to lay at your doorstep, but I sure am laying it at the doorstep of the administration because I am the guy who receives the budgets. Brother, they take the strongest in this society, and you get all you want. God help you if you can't speak for yourself.

Mr. KUSSEROW. Mr. Chairman, I think it will be helpful if you could focus on what I think the source of a lot of the problem is. The legislation and the implementation of the legislation has so categorized the services to be performed that it, in fact, has tied the hands of a lot of people who are delivering the services. Then what they wind up doing is trying to get around the shackles that have been placed on them. They begin to miscategorize what they are doing. Then, we have the auditors come in and find that they are not doing what the law requires.

Senator WEICKER. I think that is true. I think you made a perfectly appropriate statement. Let me say this, whether it is toilet training, or whether it is brushing of teeth, or caring for one's own personal hygiene, obviously, in these circumstances, it does require an extensive educational procedure. If I were an auditor, I would apply it rather broadly.

Let's see how it is being applied. I will talk to Mr. Zitley when he testifies. I agree with you that this is the leg that your auditors are standing on. But I just have a feeling that given the opportunity to be narrow saves a few bucks, some of them might be a little narrow.

AUDIT APPROACH

Mr. KUSSEROW. The auditor's approach is that they want to ensure that the law is being carried out.

Senator WEICKER. But the law in this instance, as I said before, when you say, "

> Each resident who does not eliminate appropriately and independently must be in a regular and systematic toilet training program, and a record must be kept of his progress in the program.

That is more than just patting someone down on the head, if you will. It involves the thought process. It involves a great deal. I know because I have been involved in this process in my own family.

Are the auditors in this particular instance, are they well-versed in the matter of mental illness and mental retardation?

Mr. KUSSEROW. No; but at the same time, the staff of these facilities are shackled by the very categorical nature of the funding. I would very much like, when there is more time, to discuss this matter further with you because I think there are some remedies that can be implemented that are really outside the control of our office or our Department.

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Senator WEICKER. Counsel indicates correctly, I have asked for 4 years that the Secretary issue regulations on this, and apparently we have gotten nowhere.

Mr. KUSSEROW. If you would like to pursue that issue further, I would be happy to do that with you.

Senator WEICKER. The answer is that I would, and the answer is that Mr. Doyle will be in touch with you, and I will be glad to sit down with you also.

Senator Byrd, do you have any questions on this particular subject?

Senator BYRD. No.

Mr. KUSSEROW. Mr. Chairman, may I add one final thought on this subject before we move?

Senator WEICKER. Yes.

Mr. KUSSEROW. The rule that we have as the independent auditor, the inspector and investigator of the program, is one of gathering facts. What we are really talking about here is that we go out and report what we find. It is the lawyers and the Department's program officials who decide the meaning of those facts.

Senator WEICKER. I can't disagree with that.

Mr. KUSSEROW. I do think that there is a lot that can be done for those people who are providing therapy and educational services so that they may be able to have a little bit more freedom in making decisions than they have under current law. That is why I really would like an opportunity to pursue this matter further.

Senator WEICKER. The answer is that it will be pursued further. What I intend to do now is to submit the rest of the questions for response to the record, both from myself and other Senators.

I would very much appreciate your sitting down with John Doyle at the earliest possible time, and I will try to get involved in this process in fairly short order. We will leave the questioning at that and I am going to ask that you do stand by while Mr. Zitney is good enough to appear before the committee for a few minutes, and maybe I can get some comments from him.

Mr. KUSSEROW. Thank you, Mr. Chairman.

Senator WEICKER. This is no way a requirement, because I gather that you just dropped in here to renew acquaintance with John Doyle. But it does afford us a little bit of an opportunity to get the other side of the coin here. I realize that you can't speak in an official capacity, but I wonder if you might comment on this problem in general for the committee to give us a little bit of insight as to what the difficulty is.

Mr. ZITNEY. Thank you very much, Senator Weicker, and Senator Byrd.

Senator WEICKER. Let the record show that this is Mr. George Zitney of Massachusetts, who is Mental Retardation Commissioner of the State. Is that right?

Mr. ZITNEY. That is correct.

I don't believe that the issue is one of miscategorization. I would like to really take exception to that. I don't think that we are miscategoriz-

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ing in providing services to mentally retarded people. Quite frankly, I think if you would take a look at the people who live in our ICF facilities today, everyone would recognize that those are severely and profoundly handicapped individuals who require a very comprehensive rehabilitation program.

The regulations are very, very clear. There is no room in the regulations for interpretation. It requires you to provide feeding programs, toilet training programs, or programs that enhance the person's life to live. In fact, those programs are mandatory. They are not subject to anyone's interpretation.

If you look over the last 20 years, you will recognize that 20 years ago a person who was severely retarded or moderately retarded was perhaps written off as not being capable of doing anything else. That is the sins of our past. We have come a long way in 20 years to today when we know that all retarded people, regardless of their level of retardation, can learn and grow and be trained.

For example, if you are profoundly retarded, you cannot hold up your head because you don't have the muscle control, therefore, you can't feed yourself. Your body will turn over, and, in fact, eventually you may expire. To my way of thinking, to the professionals in the field, providing that person with physical therapy and a neck training program to hold up their head so that in fact they can get into a feeding program is educational. That is education for that person. There is no other way of defining it, that is an educational program.

If, in fact, we take seriously the requirements of this legislation to provide those services to a person, regardless of age, regardless of disability, then we have to move forward with it.

When, in fact, we look at the issue of miscategorization, and that is called an educational program, as a parent, I am sure that most parents would like to know that their son or daughter is in an educational program or rehabilitation program. Don't all people go into education for the rest of their lives? We all are.

In addition, if we look at retarded people, we know that today we are trying to get all people independent, as independent as possible, so that if you hold up your head, you are much more independent than if, in fact, you have to have somebody do that for you all the time, if you can feed yourself or learn to swallow.

One of the problems that we are having with the audit is that all programs today require a very comprehensive assessment written by a team of professional people on an interdisciplinary basis, that know the client, know the assessment, know the diagnosis, and know the training that is required. All of those people have as a goal independent living, or training to the best of the person's ability.

We call that in Massachusetts, work, because all adult people work. So that, in fact, one of the problems with labeling, if we put a person in a prevocational training program, it is disallowed. If it were strictly into a medical rehabilitation program, it would be allowed. That is not just a labeling question, that is a question of an individual's opportunity to have work like everybody else.

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So we are concerned about the audit. We are willing to work with the committee, work with anyone, to resolve those issues so that in fact we can go on and provide the necessary services for all retarded people.

Quite frankly, we are happy to be here today, and it was coincidental that I stopped by, but certainly we will be happy to work with anyone in regard to this problem and to try to solve it. We do our best in our facilities. As you know, in Massachusetts, we have five consent decrees in our State because of five class action suits, and we are working very hard to provide adequate treatment in all of our facilities, and we are working very closely with the Federal Government to do that.

Thank you very much.

Senator WEICKER. Let me ask you about the point that was raised by the inspector general. Would it be helpful, without either laying at the doorstep of the State the fact that you are expanding the law as much as possible, or at the inspector general's that he is trying to restrict the law as much as possible, would it be helpful to all parties if the requirements of the law were further defined, either by law or by regulation?

Mr. ZITNEY. If we could explicate what after treatment means, if we could have a satisfactory definition, I think that it would be helpful to all of us because it is so subject to interpretation by a surveyor or by an auditor, and quite frankly it is a problem for all of us.

Senator WEICKER. Senator Byrd.

Senator BYRD. No questions.

Senator WEICKER. Senator Andrews.

Senator ANDREWS. I have no questions.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. Thank you very much for your impromptu testimony. It has been very, very helpful.

Mr. ZITNEY. Thank you.

Senator WEICKER. I thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

WITHHOLDING OF MEDICAID FUNDS FOR TRAINING IN ICF/MRs

Question. Mr. Kusserow, I understand your office has recommended withholding approximately $34 million in Federal Medicaid funds from several states for training services provided to residents of Intermediate Care Facilities for the Mentally Retarded (ICF/MRs). You further estimate that up to $585 million could be saved over the next five years if these funds continue to be withheld in other states. Why are these funds being withheld, which I understand are used for such required activities as toilet training and self-feeding skills?

Answer. We did not question expenditures allowable under applicable Federal legislation, Health Care Financing (HCFA) regulations, or state law. Rather, the issue raised in our reports pertains to expenditures charged to Medicaid that should have been charged to other programs, according to applicable Federal and State laws.

Question. Do you believe that denying Medicaid funds for such training of mentally retarded persons is cost effective?

Answer. We believe that providing Medicaid funds to support active treatment as defined in statute and HCFA regulations is both cost effective and appropriate.

Question. When a State furnishes ICF/MR residents with "active treatment services," as required by Federal law, we are being told such expenditures will be treated as non-allowable costs. On the other hand, should the State fail to provide such services, our ICF/MR facilities will be decertified for failure to comply with the statute and minimum Federal standards. Isn't your recommendation creating a Catch 22 situation?

Answer. We have never raised any issues with respect to the provision of active treatment. Rather, our reviews have focused on whether active treatment was being provided as required by HCFA regulations. Active treatment is reimbursable under Title XIX.

MEDICAID FRAUD CONTROL

Question. What assurances can you give us that the States will continue to make the same level of effort to identify fraud in the Medicaid programs?

Answer. The proposed growth limits on Medicaid costs give States every incentive to reduce costs and assure funding for operations such as the MFCUs that reduce Medicaid costs with recoveries of misspent funds. We must also remember that these units are creatures of State statutes and have a base of support in their state.

Question. How do you expect to maintain consistent oversight and training efforts if the block grant is approved?

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Answer. The legal relationship between OIG and the State Medicaid Fraud Control Units will change if the block grant legislation is passed. The legislation would probably reduce the OIG's role in certifying these units, but will not necessarily affect OIG's role in providing them training and technical assistance--here the key factor is the quality of OIG support. In any event, we expect the current high degree of coordination and cooperation with the Units to continue.

Question. How did you arrive at the expected 10 percent increase in convictions given the block grant proposal?

Answer. The 10 percent increase in MFCU convictions was based on growing productivity and maturity of the MFCUs and assessment gained from the existing oversight procedures by considering:

- o the effectiveness of past training;
- o the maturation of newer MFCUs into more effective organizations, particularly in the areas of fraud investigation and detection; and
- o results of assistance rendered by Office of Inspector General personnel to various MCFUs.

PHYSICIAN FEE FREEZE

Question. Last year Congress enacted a physician fee freeze for doctors practicing on Medicare and Medicaid beneficiaries. We also gave the Secretary the authority to sanction doctors who violate that freeze. Has that sanctioning authority been used yet?

Answer. In August 1984, the Health Care Financing Administration issued instructions to Medicare carriers concerning the identification and development of cases involving non-participating physicians who raise their charges in violation of the fee freeze. These instructions require that the carrier take the following actions:

1. routinely monitor the charges of all non-participating physicians to detect potential violations;
2. investigate all beneficiary complaints to determine if there is merit to the complaint;
3. in cases where there is a suspected violation, send a warning notice to the physician and give the physician an opportunity to either show that he/she did not violate the freeze or to correct his billing pattern; and
4. closely monitor the charges of physicians who are served warning notices and where appropriate, refer such cases to the Office of Inspector General (OIG) for a sanction determination.

Several thousand physicians who are suspected of violating the fee freeze have been identified by the carriers.

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The OIG, because of the time requirements which permit physicians to alter their behavior after being warned by carriers, has not received any referrals from the carriers at this point. However, we expect cases to be referred to OIG in a few months.

We will handle these cases in accordance with our established Civil Monetary Penalty and administrative sanction procedures.

BUDGET--TRUST FUND REIMBURSEMENTS

Question. In FY 1984 Social Security trust funds made up 9 percent of your total budget request. In FY 1986 you are requesting a $70 million budget with trust funds at $30 million or 43 percent of your total budget. Please explain how the trust funds will be used and why this increase has been so dramatic?

Answer. This budget proposes an increase of $10 million in reimbursements from the Social Security and Medicare trust funds to more accurately reflect OIG work dedicated to programs financed by these trust funds. Since 1981, the number of OIG staff devoted to review of the Social Security and Medicare programs has increased substantially, including the transfer to the OIG budget in FY 1983 of "Program Integrity" resources formerly included in the budgets of the Social Security Administration and the Health Care Financing Administration. This $10 million increase in trust fund reimbursements provides the Congress a more accurate representation of the amount of work performed by OIG in the trust fund programs.

Those functions that were transferred to the OIG were initially funded with OIG direct appropriations. We are now correctly showing that effort as chargeable to trust funds. In addition, we are devoting more and more resources to support the trust fund programs, and, as a result of that shift, we are returning to the trust funds far more than is used to support our efforts.

Question. By increasing your attention to the major dollars programs, are you neglecting necessary audits of other programs where fraud and abuse occur?

Answer. I expect you're referring to my redirection of OIG attention to HHS' big-dollar programs, namely Social Security and Health (Medicare and Medicaid). The redirection has been and continues to be a success. In 1981, total OIG savings, fines, and recoveries were $165 million; in 1984 our savings total was $3.7 billion--a 2,000 percent increase.

To accomplish this redirection, I have, of course, shifted resources from other programs. For the most part, we've redirected resources from determining the allowability of grant and contract costs claimed by colleges/universities and State and local governments and from reviewing contract closing statements. However, we are in no way neglecting the necessary audits of these programs.

Rather, we are relying on non-Federal auditors to provide basic audit coverage of financial and compliance issues at these organizations. This approach is consistent with the concepts of the Single Audit Act of 1984. Further, the non-Federal auditors evaluate the management systems controlling Federal activity and do

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limited tests of direct and indirect costs charged to Federal programs, preferably annually. These reviews provide us a broad perspective of each entity's overall management system and identify any problems that we may need to follow up on. Also, we perform audits of institutions' indirect cost proposals and State and local cost allocation plans when problems are noted or when a specific request is received from the Department's cost allocation staff.

Question. Aren't you sending a signal that the smaller programs are now fair game?

Answer. No. As previously mentioned, we are relying on non-Federal auditors to provide audit coverage in areas where we are not expending large resources. And, on a selected basis, we are using our staff. By making use of computer technology, new developments in statistical sampling, and a new breed of highly sophisticated and highly trained audit and investigative staff, we have been able to greatly increase our oversight accomplishments. I believe this will discourage any grantee or contractor from believing that these programs are fair game.

ADDITIONAL RESOURCES

Question. You are telling this committee that with your present effort you will recover or save $4 billion in FY 1986. It would seem that you would save more by increasing your level of effort and staff. However, last year you told this committee that you would not request additional resources until you were confident that the existing resources were operating at a maximized level of productivity.

You are still not requesting additional resources. How long will it take you to achieve maximized productivity?

Answer. I will not ask for more resources until I am convinced that we are using our resources to maximum efficiency. As long as we are on that growth path, I can't come to you and say that we have reached maximum efficiency. There will come a day when I will come before you and say, I cannot achieve any more in outputs without additional resources.

I cannot honestly say I have reached that point.

RESCISSION

Question. You are requesting a rescission or withholding of $850,000. I understand that this will restrict travel and reduce consultant services. Does this mean you will be doing less auditing in remote areas?

Answer. In response to the proposed rescission of $496,000 pursuant to the Deficit Reduction Act of 1984 and the $354,000 withheld pursuant to the 1985 Treasury-Postal Services Appropriations Act, we have capped the Office of Audit's travel funds at the level originally proposed for Fiscal Year 1985. Our Office of Audit plans to absorb the entire amount in the contract audit area, which would have little or no impact on our audits in remote areas.

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Question. Will this reduce the number of audit contracts and thereby decrease the amount of dollars recovered?

Answer. The number of contract audits will, in fact, decrease. However, we do not expect any material change to dollar savings or recoveries. The reason is that contract audits usually involve less sensitive and less costly program areas and yield a much smaller rate of return for dollars spent than direct OIG audits.

PROSPECTIVE PAYMENT SYSTEM

Question. What role has the OIG played in the process of implementing the Prospective Payment System (PPS)?

Answer. The OIG will continue its major ongoing initiative of monitoring the Medicare Prospective Payment System. Through a combination of in-house and contractual efforts, major studies and analyses will be conducted which validate the assignment of Diagnosis Related Groupings (DRGs) and payouts to hospitals.

In accord with Congressional guidance, OIG will evaluate the Prospective Payment System in terms of the way in which the Health Care Financing Administration (HCFA), the Peer Review Organizations (PROs), and the Intermediaries are implementing the various elements of the program. Reports of the cost effectiveness and maintenance of quality care will be provided to the Congress on an ongoing basis. The OIG has made several significant studies as a part of this overall effort. We have reviewed and commented on proposed regulations and policies implementing both PPS and the Peer Review Organizations (PROs), one of the major controls on abuse of the system.

We have closely reviewed the individual diagnostic related groups (DRGs) and identified problems with specific diagnoses and procedures in certain DRGs. These include:

- o DRG 129 - Cardiac Arrests. As a principal diagnosis, this means a patient was admitted dead. Another principal diagnosis is usually appropriate. Usually, the cardiac arrest occurs at the end of the stay (the patient dies).

- o Nail removal is classified as an operating room procedure and under PPS will cause a patient's stay to be reimbursed in a higher paying DRG.

- o Percutaneous Transluminal Coronary Angioplasty, an alternate approach to coronary bypass surgery is included in the DRG for open heart surgery resulting in hospitals receiving considerably more than the DRG weight contemplated. This could result in overpayments of more than several million dollars on fiscal year 1985 if not corrected.

- o DRG 39 - Lens Procedures. Some hospitals were submitting additional (and unnecessary) surgical information in order to receive payment in a higher paying DRG. The Health Care Financing Administration accepted OIG's recommended change in order to prevent this inappropriate payment. Savings

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from this modification are estimated to be $4 million annually.

We will be conducting an ongoing review of PPS to identify changes in cost and utilization in a representative sample of hospitals subject to the system. This will allow us to determine the effectiveness of both PPS and the controls on the system such as PROs, and develop mechanisms for targeting abusers of the system.

Question. What have been some of your findings?

Answer. We are concerned about some problems we have discovered in the system. These include:

- Premature discharge and subsequent readmission of patients in need of inpatient care and the inappropriate transfer of patients from PPS hospitals to other hospitals or units.

  We recently issued a report to the Health Care Financing Administration (HCFA) noting that while HCFA has the authority to deny payment or require corrective action on a case-by-case basis, they have not been taking such action in these cases. As a result of our report, they are revising instructions which would require Peer Review Organizations (PROs) to deny payment and take corrective action in cases of readmissions and transfers involving medically inappropriate practices.

- Problems with individual Diagnosis Related Groups (DRGs). We have conducted an in-depth analysis of the DRGs, identifying specific DRGs that need modifications and areas of potential abuse. We have suggested revisions to the DRGs and to the software program that groups the DRGs.

  These revisions include problems for lens procedures, angioplasties (an alternative to by-pass surgery), cardiac arrests, and nail removals as an operating procedure. HCFA has agreed to the changes for lens procedures and angioplasty, which should lead to savings of over $5 million annually. We are waiting for a response from HCFA on the other issues.

We are also conducting studies of three DRGs:

- Lung Cancer--DRG 82
- Chronic Lung Disease--DRG 88
- Strokes--DRG 14

These are three frequently occurring DRGs that our pilot studies showed contained a high number of errors. We are conducting reviews to determine the amount of overpayments that result from coding errors in these DRGs.

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SPACE RENOVATION

Question. You are requesting space renovation costs of $1.3 million. Also, you are reducing the number of square feet utilized by your office. Please explain the rationale for this proposal and how will this save on space usage in future years?

Answer. The budget proposes that the amount of office space for OIG employees will decrease during FY 1986 as part of the Department's efforts to reduce office space. These space reductions are expected to reduce Standard Level User Charge (SLUC) costs by $314,000. Offsetting the decreased $314,000 in SLUC costs is a proposed $1,350,000 increase to renovate and alter OIG office space. This nonrecurring cost increase is expected to permit further reductions in office space in FY 1987. The renovation and space consolidation effort is consistent with the President's goal of reducing office space to 135 square feet per employee. The budget fully anticipates that this $1,350,000 investment will be "paid back" in future year budget savings through reduced office space rental charges.

COMPUTER FRAUD

Question. Fraud through the misuse of computers seem to always be in the news. Have you developed any methods to deter this type of activity in Departmental programs?

Answer. Since becoming the HHS Inspector General, I have made integrity of our computer systems one of my top priorities.

- I created the first EDP audit division in the IG community. One of its major activities is to oversee the massive systems modernization plan that is going on at the Social Security Administration.

- In 1982, under the aegis of the President's Council on Integrity and Efficiency, I directed a governmentwide study of computer fraud and abuse. The resulting report, "Computer-Related Fraud and Abuse in Government Agencies," published in June 1983, received much interest and served to heighten the awareness to this growing problem and our need to safeguard our computers.

- As a followup to the 1983 study, we have interviewed 46 perpetrators of computer-related fraud to gain their perspectives on why, how and in what work environment they were able to "rip-off" our systems. The report of this study will be published shortly.

- Last summer, I co-hosted with former Treasury Assistant Secretary Richard Shriver, a one-day seminar on computer security for Inspectors General and Assistant Secretaries for Management. The seminar served to heighten the awareness of both communities to the vulnerabilities of our systems and helped establish an ongoing dialog between the two groups.

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- Also under the aegis of the PCIE, I chair a work group on EDP Systems Review and Security, which has the active participation of staff of the HHS Assistant Secretary for Management and Budget. The objective of this work group is to facilitate audit review of automated information systems under development to increase the likelihood that auditable and properly controlled systems are being developed. The final product of this effort is an audit guide for the entire systems development life cycle.

WORK FOR OTHER AGENCIES

Question. In 1984 you were able to achieve over $2 million in reimbursements from other Federal agencies for work done for them. You are only projecting $200,000 in FY 1986. Why is that?

Answer. As previously stated, the OIG has redirected most of the resources used in audits of universities and non-profit organizations to performing high priority audits of the Medicare, Medicaid and Social Security programs. Much of the previous audit workload is now being covered by non-Federal auditors under OMB Circular A-110. In those cases where OIG resources are committed to audits at universities and non-profit organizations, we include funds awarded by other Federal agencies in our audits and bill them accordingly, in compliance with OMB Circular A-88, which provides for reimbursement for audit work performed on behalf of other Federal agencies.

BUDGET REQUEST FORMAT

Question. Last year's budget request proposed specific amounts for each of your major operational offices--i.e., Office of Audit, Office of Investigations, Office of Health Financing Integrity and Office of Inspections. For the past two years you have felt it necessary to request permission for reprogramming of funds among these operational offices. I note that in the FY 1986 request you have consolidated these separate operational offices. Will this consolidation give you more flexibility to respond to changing program necessities?

Answer. Yes, we have been considering for some time changes to our budgeting system which would improve our capacity to manage our resources. One of those changes is to combine our budget request for the four operating components into a combined activity called "Program Operations." Our primary objective is to give ourselves management flexibility to quickly focus resources on new problems and others targets of opportunity and to respond to Secretarial and Congressional priorities. Additionally, it is a better portrayal of the close management and working relations between the different OIG offices. The OIG frequently conducts joint investigations for certain issues. This collaborative use of OIG operating component offices brings to the problem an optional mix of operating office skills and perspectives, thereby maximizing the return to the taxpayers.

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Question. In your budget justifications in the future, please provide the Committee with information on how much funding was provided to each operational office in the prior three fiscal years?

Answer. We certainly will. The following is the information you requested for the last three fiscal years:

($ 000)

	FY 1983	FY 1984	FY 1985
Audit	$33,034	$35,677	$38,773
Investigations	18,527	18,442	19,157
Health Financing Integrity	9,219	10,646	10,014
Program Inspections	3,014	2,964	2,920
Program Operations	$63,789	$67,729	$70,864

SECOND SURGICAL OPINIONS

Question. Your office did an extensive review and audit of the need for mandatory second surgical opinions in the Medicare and Medicaid programs. This report was issued in 1983. Now that we have implemented the prospective payment system, do you still believe that there is a need for mandatory second opinions?

Answer. You asked if I believe a mandatory second opinion program is still needed in view of the Department's implementation of the Prospective Payment System. Based on testimony at the recent hearing, I assume you mean the Peer Review Organizations (PROs) that have been established by the Department.

For several reasons, I believe that a mandatory second opinion program is still needed for Medicare in spite of the establishment of the PROs.

First of all, PROs deal only with medical procedures that are to be performed in hospitals. Since some of the procedures most susceptible to second opinions can be performed in an out-patient setting, there is the likelihood that many potentially unnecessary surgeries will be performed without PRO review.

Secondly, there is a major difference in both the purpose and operation of a mandatory second opinion program and a PRO. Mandatory programs have just one objective--to reduce the number of elective surgeries. They accomplish this in two ways. First, mandatory programs influence patients' behavior by encouraging them to be more informed and involved in decisions on their health care. Their aim is to provide patients with sufficient information so that they can make intelligent decisions regarding surgery or the alternatives to surgery. Secondly, mandatory programs influence

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physicians' behavior through the "sentinel effect." This is a phenomenon whereby physicians initially recommend fewer surgeries because they know that their decisions to operate will be reviewed by other physicians.

PROs, on the other hand, have eight separate objectives, most of which deal with the appropriateness of admission to hospitals versus use of ambulatory surgical centers or other outpatient facilities. There is one objective relating to reducing unnecessary surgery, but since PROs will have no contact with beneficiaries, this objective can be achieved only through the sentinel effect or outright denial through pre-admission screening of medical records or other documents. The effectiveness of both the sentinel effect and pre-admission screening depend wholly on what is to be reviewed by the PROs.

In summary, pre-admission reviews, as proposed by the PROs may prevent surgeries in the most obvious of cases. They will not, in my opinion, prevent surgeries that may be appropriate based on a review of medical records but could be replaced by alternate methods of treatment had the beneficiary been aware that such treatment was available.

MEDICARE PART B DEDUCTIBLE

Question. Your office recently issued a report entitled "The Medicare Part B Deductible Needs to be Raised Now to at Least $100 and Indexed." What was your basis for issuing that report?

Answer. As part of our effort to evaluate the efficiency and economy with which Medicare and Medicaid are administered, we study effective management practices in the private health insurance industry. Our aim is to identify good controls in the private sector which can be utilized in Federal health programs. We then advise Department officials who are responsible for managing the programs and making policy suggestions to Congress or our findings and recommendations.

Our review of the Medicare Part B deductible disclosed that private health plans widely use the deductible as an effective cost containment control, including discouraging unnecessary utilization of services. In this connection, we found that most plans had minimum deductibles of $100 and many had far greater amounts than that. We advised HCFA of the results of our study and showed how the Part B deductible is too low in comparison to those of private industry. Our report should be helpful to HCFA, particularly as HCFA has had an interest in this area for some time.

PROSPECTIVE PAYMENT SYSTEM

Question. The Secretary testified extensively on the progress the Department has made in implementing the Prospective Payment System. What role has your office played in this process? What have been some of your findings?

Answer. The OIG has been very active in identifying some problems in the system. These include:

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- o The premature discharge and subsequent readmission of patients in need of inpatient care and the inappropriate transfer of patients from Prospective Payment System hospitals to other hospitals or units. As a result of our findings, HCFA is revising the instructions which would require peer review organizations to deny payment and take corrective action in cases of readmissions and transfers involving medically inappropriate practices.

- o Problems with individual diagnosis related groups (DRGs). We have conducted and indepth analysis of the DRGs, identifying specific DRGs that need modifications and areas of potential abuse. We have suggested revisions to the DRGs and to the software program that groups the DRGs. Studies are currently being conducted in three areas. These are lung cancer, chronic lung disease, and strokes.

In addition, we will be analyzing changes in utilization, costs, and payments in a major study of hospitals subject to PPS regulations.

CIVIL MONETARY PENALTIES LAW

Question. In 1983, your office received two new authorities--the sanctioning authority and the civil monetary penalties authority. Can you describe your success with these programs? Have you found any weaknesses or loopholes for health care providers to slip through?

Answer. The success of the CMPL is best demonstrated by numbers. To date, we have collected $12,513,224 in penalties, interest, and overpayments. This is for FY 1983, 1984 and through March 15, 1985. In 1985 alone we have had 18 settlements where the medical providers have agreed to pay $1,890,407, and the Department of Justice has retained three of our cases, which have minimum potential of $300,000. In addition, we have 120 open cases in our CMPL workload. The sanctioning authority has been just as successful. Administrative sanctioning by the OIG has led to 93 health care providers being "kicked out" of HHS' Medicare and Medicaid programs. Investigations of Medicare/Medicaid fraud resulted in 234 convictions and financial recoveries and savings of over $27 million.

There are, however, some loopholes which need to be tightened. The OIG has made several recommendations to alleviate these weaknesses. These would have the effect of improving the Secretary's authority to impose civil monetary penalties by changing some of the technicalities of the present legislation and by increasing the state share of CMP awards to encourage state investigation and referral of Medicaid fraud cases.

Some changes which would be made in the sanctioning authority would include an exclusion of health care professionals from Medicare and Medicaid participation based on findings of inferior care or inappropriate conduct resulting in a revocation or suspension of a license by a state licensing authority. Also, it would exclude any individual or entity that has been convicted of: (1) fraud and financial abuse, or neglect or abuse of patients in connection with

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the delivery of health care or a Federal, State, or local government program; or (2) the unlawful manufacture, distribution, or dispensing of controlled substances.

HOME HEALTH SERVICE

Question. What current activities are being undertaken by the OIG in the area of Home Health Services? What is the status of the reports to Congress on this subject?

Answer. Based on survey work completed in our Dallas region, extensive nationwide audit and inspection activities are presently being conducted in FY 1985. The Office of Inspector General envisions these reviews to result in separate and independent audit and inspection study reports that should clearly demonstrate what changes are needed to achieve significant program savings.

The Office of Inspector General is looking into ten areas including:

- o an evaluation of the patient's homebound status;
- o an evaluation of the adequacy of provider survey and certification activities;
- o an evaluation of the allowability and reasonableness of cost report data;
- o an evaluation of the problem of overutilization of services and Home Health Agency (HHA) visits;
- o an evaluation of the effectiveness of the cost containment methodologies;
- o an evaluation of services provided to patients by Intermediate Care Facility-based HHAs;
- o an evaluation of excessive Durable Medical Equipment payments in home health care;
- o an evaluation of the need for financial security requirements;
- o an evaluation of problems involving chain organizations and intermediary fractionalization; and
- o an evaluation of excessive and duplicate care.

As a part of the first of these indepth studies, OIG reviewed submitted cost reimbursement data from 374 HHAs to determine if savings could be realized by applying HHA cost limits by type of services. We found that savings of $2.9 million would have been realized for periods covered had HCFA applied cost limits by type-of-service rather than in the aggregate. Nationally, it is estimated that program-wide savings could amount to approximately $35 million annually.

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INVESTIGATIVE SUCCESS

Question. In the last two years, your office has shown remarkable progress in the number of prosecutions and convictions. Am I correct in assuming that you have established better working arrangements with the Department of Justice? What other factors have contributed to your success rate? Can we expect the same in FY 1986?

Answer. Yes, we expect our success to continue in FY 1986. Our entire investigative program evolves around the idea of directing our investigative resources into those areas where they can be the most effective. There are several factors which have helped us increase our number and rate of prosecutions and convictions. Yes, closer cooperation with the Department of Justice (DOJ) is one of them. This is particularly true in cases involving the health care programs of this Department. However, this cooperation with DOJ is only part of our overall investigative strategy which, I feel, is responsible for our success.

To begin with, we are attempting to turn the bulk of our resources away from reactive type investigations and are, instead, redirecting our efforts into proactive investigative projects. Because proactive projects develop from the identification of a systemic weakness, they have proven themselves very effective in identifying large numbers of cases which have a high level of prosecutive potential. In addition, such projects are very cost-effective and allow us to select our targeted area of concentration.

Another aspect of our strategy is to work closely with other investigative agencies on task forces. Here is where our cooperation with DOJ has paid off. By working closely with other agencies such as the FBI and Secret Service on joint investigations and task forces, we have been able to gain the early involvement of Federal prosecutors in our cases. This early involvement has developed a much higher level of prosecutor interest in our cases.

Finally, we are working much more closely with program agencies to help screen referrals to us so that we may pursue only those cases which appear to have prosecutive potential. This avoids our wasting valuable resources on unproductive investigation.

COMPUTER MATCHING

Question. Last year, your office was heavily involved in computer matching and computer security activities. Is your involvement now decreasing?

Answer. We have a number of significant activities underway in the areas of computer matching and computer security. With respect to matching, my office:

- is participating in the development of regulations to implement the income eligibility verification procedures required by the Deficit Reduction Act (DEFRA);

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- o is developing a final set of standardized computer matching formats and procedures required under DEFRA. The final formats are being based on results of extensive field testing by State welfare and labor agencies. The field tests were done under contract with my office;

- o released in March a draft "Catalog of Automated Front-End Eligibility Verification Techniques" to assist States considering implementing front-end techniques or enhancing their systems. The catalog is particularly timely given the DEFRA regulations;

- o is completing a comprehensive study of the Social Security BENDEX system to assist States to better utilize this data base to verify social security and other benefits; and

- o will be participating in a panel discussion sponsored by the Office of Technology Assessment on the implications of Federal Government Information Technology for Congressional Oversight and Civil Liberties.

With regard to computer security:

- o As a follow-up to our 1983 study "Computer-Related Fraud in Government Agencies" we have interviewed 46 perpetrators of computer-related fraud to gain their perspectives on why, how and in what work environment they were able to "rip-off" our systems. The report of this study will be published shortly.

- o Last summer, I co-hosted with former Treasury Assistant Secretary Richard Shriver, a one-day seminar on computer security for Inspectors General and Assistant Secretaries for Management. The seminar served to heighten the awareness of both communities to the vulnerabilities of our systems and helped establish an ongoing dialog between the two groups.

- o Also under the aegis of the PCIE, I chair a work group on EDP Systems review and Security, which has the active participation of staff of the HHS Assistant Secretary for Management and Budget. The objective of this work group is to facilitate audit review of automated information systems under development to increase the likelihood that auditable and properly controlled systems are being developed. The final product of this effort is an audit guide for the entire systems development life cycle.

PHONY MEDICAL DOCTORS

Question. We have heard a lot about phony doctors and bogus medical degrees. Is your office involved in this area? If so, what have you been doing and how serious is the problem?

Answer. Names of approximately two hundred phony physicians were matched against bills received by State Medicaid agencies and Medicare intermediaries and carriers to determine if they had submitted any bills to Medicare or Medicaid. We have uncovered eleven

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cases in which individuals have requested Medicare or Medicaid reimbursement. For these cases, we are in the process of taking action to suspend payment and to exclude these providers from program participation.

We are working very closely with local and State authorities to determine if any individuals with improper credentials are in hospital residency programs. In cases where Postal Inspectors could indict and convict individuals on a violation of mail fraud laws, or where other sufficient evidence of falsified credentials exists, we could then pursue additional criminal civil or administrative actions. They could be charged with either submission of false claims or misuse of Federal Medicare or Medicaid monies while paid as an employee of a hospital.

We are also approaching this problem from another perspective. We convened an informal group of public and private sector representatives concerned with the effect this issue would have in the medical community and beneficiary population at large. Attending were representatives from the Postal Inspection Service, the American Medical Association, the Educational Commission for Foreign Educational Graduates, the Federal Bureau of Investigation, the Federation of State Medical Boards and the Department of Health and Human Services. Even though informal, with no major objectives other than the establishment of new lines of communication, the convening of this meeting was significant since it represented a new merging of traditional medical and law enforcement institutions. We wanted to share information and stay on top of the issues.

We recently held our second meeting to inform all representatives of the progress being made in the various investigations. As a result of these meetings, we are receiving names of practitioners with possible fraudulent licenses from sources other than the Postal Service.

PROGRAM OPERATIONS

Question. Your budget justification refers to Program Operations. Does this mean a reorganization of your office?

Answer. The FY 1986 OIG Justification consolidates the different OIG operating components (i.e., Office of Audit, Office of Investigations, Office of Health Financing Integrity and Office of Program Inspections) into a single activity entitled "Program Operations". This consolidation better reflects the close management and working relationships of the different OIG offices. The OIG frequently conducts joint investigations for certain issues. This collaborative use of OIG operating component offices brings to the problem an optimal mix of operating office skills and perspectives, thereby maximizing the return to the taxpayers. The collaborative approach, however, occasionally blurs distinctions of budget resource estimates across the operating component activities. The proposed consolidation into a single Program Operations activity more accurately portrays for the Congress how OIG resources are actually used.

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INVOLVEMENT IN PCIE ACTIVITIES

Question. What is the extent of your involvement in PCIE activities? Do you believe that these activities are bearing fruit on an intergovernmental basis?

Answer. The PCIE report "The First Four Years and Future Directions" documents IG accomplishments over the past four years. The PCIE's coordination has succeeded in areas where prior individual IG efforts could not. Significant accomplishments include:

- o $46 billion in total monetary impact,
- o $273 million in recoveries and 10,000 successful fraud prosecutions,
- o 2,600 actions against contractors, and
- o 6,700 actions against Federal employees.

My involvement with the PCIE includes:

- o Chair, Computer Security Project,
- o Chair, Legislative Committee,
- o Chair, Medical Provider Fraud Project,
- o Co-Chair, Computer Matching Committee,
- o Member, Prevention Committee,
- o Member, Planning Committee & Productivity Task Force, and
- o Member, Telephone Communications Committee.

QUESTIONS SUBMITTED BY SENATOR WILLIAM PROXMIRE

HCFA PROGRAM IMPROVEMENTS--SAVINGS

Question. Mr. Kusserow, in your opening statement you refer to program changes that were identified by your shop that could result in over $1 billion in savings by the Health Care Financing Administration. The operative word is "could." In my experiences, HCFA is very resistant to program changes. How much will HCFA save in the current fiscal year as the result of implementing your recommendations?

Answer. In my two Semiannual reports for FY 1984, I reported total savings of $1.5 billion in the health area as a result of HCFA or Congressional action on IG recommendations. Let me point out, though, that the reports that comprise this savings figure were not all issued in FY 1984. The reason, of course, is that many involved legislative recommendations requiring Congressional approval. The majority of reports which comprise the $1 billion "potential" savings figure that you refer to are still under consideration by the Department.

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Question. We will be hearing from HCFA tomorrow. It would be useful if you could tell us today what three or four recommendations you have made over the past two years would produce the greatest savings if HCFA agreed to implement them.

Answer. Three good examples come immediately to mind: (1) mandatory second surgical opinion programs for Medicare and Medicaid, (2) round-down of Medicare Part B claims, and (3) slowing Medicare Parts A and B payments to a 30-day cycle.

1. Studies on Second Surgical Opinion Programs (SSOPs) consistently point out that mandatory programs are effective in reducing unnecessary surgery. For example, one study showed mandatory programs covering just the more common procedures could reduce surgeries nationwide by as much as 29 percent in Medicaid and 18 percent in Medicare at annual cost savings of about $65 million and $135 million, respectively, using 1984 dollars.

   We had recommended that HCFA seek a legislative change to the Social Security Act that would require Medicare and Medicaid beneficiaries to seek a mandatory second surgical opinion for selected surgeries.

   HCFA agreed that unnecessary surgeries are being performed. HCFA believed, however, that the problem was best addressed by Professional Review Organizations.

2. Based on a study at two carriers, we estimated Medicare Part B could save about $45 million annually or $225 million over a 5-year period if payments for odd-penny claims were rounded, on a per claim basis, to the next lower whole dollar.

   The effect of such a policy on the individual beneficiaries or physicians/suppliers would be minimal--about 30 cents per paid claim. We proposed that HCFA seek authority to institute such a practice.

3. The Prompt Payment Act required Federal agencies to pay vendors timely. OMB Circular A-125 also called for prompt payments but cautioned that the payments should be made as close as possible to a 30-day payment cycle. This ensures that the Federal Government adheres to standard business practice and, at the same time, avoids loss of interest on its cash balances or higher interest on the public debt.

   HCFA has not required either intermediaries or carriers to apply the intent of these cash management practices in their Medicare payment systems. Rather, HCFA encourages a quick processing turnaround. In FY 1983, Medicare intermediaries paid $18.9 billion in direct billings--mainly from the Part A Trust Fund--within an average of 10.5 days. During this same period, carriers paid Part B claims totaling $13.2 billion within an average of 9.9 days.

   We estimate that the Medicare Trust Funds could earn between $1.6 billion and $2.1 billion in additional interest income

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over a 5-year period (or between $320 million and $423 million annually) if intermediaries and carriers adopted the 30-day payment cycle endorsed by OMB.

Though HCFA initially agreed with our recommendation to slow the Medicare payment cycle, no action has been taken to date.

Question. Mr. Kusserow, on March 19th I received a letter from Dr. Davis commenting on a number of recommendations your office has made for saving Medicare and Medicaid dollars. Dr. Davis disagreed with your suggestion that mandatory second opinions be required in the Medicare and Medicaid programs but said the question was still being considered. More specifically, Dr. Davis said your projection of $135 million in savings annually to Medicare was based on the assumption that the Medicaid experience is directly transferable to Medicare, but that given the differences in the characteristics and health care experience of the Medicaid and Medicare populations, this is an invalid assumption. How do you respond to that criticism?

Answer. HCFA's assertion that our cost savings estimate of $135 million annually was based on an assumption that the Medicaid experience was directly transferable to Medicare is incorrect. To the contrary, our savings estimate was based primarily on Medicare experience gained under the New York Demonstration Project which was funded by HCFA. However, even if HCFA's assertion were correct, it would not necessarily mean that our savings estimate was invalid.

Our savings estimate consisted of two separate computations. First, we estimated the number of surgeries that would be avoided because of a mandatory second opinion program. Second, we applied net savings for specific procedures to the number of avoided surgeries to arrive at an estimated savings.

HCFA's criticism as we understand it applies to our initial computation. It alleges that in estimating the number of avoided surgeries under Medicare, we used results of mandatory second opinion programs reported by Michigan, Wisconsin and Massachusetts for their Medicaid programs. This is not correct. We used the results of the New York Medicare Demonstration Project reported by Abt Associates in September of 1981.

Because the Project involved a voluntary second opinion program, we modified the results to reflect two known factors: 1) that nonconfirmation rates were lower for mandatory programs than they were for voluntary programs, and 2) that the sentinel effect played a significant role in reducing elective surgeries in mandatory programs but was virtually nonexistent in voluntary programs. The Acting Deputy Administrator of HCFA confirmed the importance of the sentinel effect in mandatory programs during his recent testimony before the Special Committee on Aging.

In our second computation, we used Medicaid net savings for specific procedures reported by either Abt Associates for the Massachusetts Medicaid program (this study was also funded by HCFA) or the Wisconsin Department of Health and Social Services for its

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Medicaid program. It is important to note that the surgeon fees used by the researchers to calculate Medicaid savings were in every case lower then the average surgeon fees reimbursed by Medicare. It is, therefore, likely that our savings estimate was understated.

To reiterate, we did not apply the extremely high rates of avoided surgeries experienced by Medicaid second opinion programs to Medicare. It would not, however, be necessarily wrong to do so. According to a draft report entitled "Second Surgical Opinion Programs: Public Policy Alternatives" prepared by Abt Associates for HCFA, the results of mandatory second surgical opinion programs can be reasonably applied to both Medicare and Medicaid since findings concerning nonconfirmation rates and participant surgery decisions are generally quite similar even across greatly differing populations.

SECOND SURGICAL OPINIONS

Question. In a response to a question submitted for last year's hearing record, Dr. Davis said that new legislation would be necessary to permit national mandating of second surgical opinions under the Medicare and Medicaid programs. Do you agree?

Answer. In my March 1983 report to Dr. Davis, I recommended that HCFA, through appropriate legislative channels, seek a change to the Social Security Act that would require all States to adopt mandatory second opinion programs for the Medicaid program, and all Medicare beneficiaries to obtain second opinions for selective surgery as a condition for Medicare reimbursement. I, therefore, agree with Dr. Davis' statement that new legislation would be necessary to permit national mandatory second opinion programs under Medicaid and Medicare.

SSA WORK MEASUREMENT SYSTEM

Question. Mr. Kusserow, last year, in a response for the record, you told us that your office had determined that a full-scale study of the Social Security Administration's (SSA's) field office work measurement system would be premature because you lacked an in-depth knowledge of SSA operations and processes. Consequently, you studied SSA operations on a program specific basis and came up with a series of guides which focus on methodologies for examining various aspects of the Social Security programs.

Have you abandoned your plans to study SSA's field office work measurement system or just postponed those plans?

Answer. We have neither abandoned our plans to study SSA's field office work measurement system nor postponed those plans. My FY 1985/86 Workplan allocates substantial resources to this assignment.

OIG - RENTS, COMMUNICATIONS AND UTILITIES

Question. Mr. Kusserow, last year you estimated you would be spending $2,366,000 in 1985 on rent, communications and utilities. Your current 1985 estimate for this object class is $356,000.

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Obviously some realignment has taken place. Can you tell us what has happened in this area?

Answer. The original Justification reflected a technical error carried forward from the President's Budget. The Department sent revised schedules to the Committees on Appropriations on March 25, 1985. These schedules show that we expect our expenditures for these purposes to remain level for Fiscal 1985 and 1986. This technical correction does not change the total amount requested for either of these fiscal years.

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CENTERS FOR DISEASE CONTROL

STATEMENT OF DR. JAMES O. MASON, DIRECTOR

ACCOMPANIED BY:

WILLIAM E. MULDOON, DIRECTOR, OFFICE OF PROGRAM SUPPORT
WILLIAM BELDON, BRANCH CHIEF, OFFICE OF BUDGET, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. We will now hear from Dr. James Mason, Director of the Centers for Disease Control, and his colleagues. I would like to make a few comments before you start, Dr. Mason.

In 1986, the President's budget proposes to spend $286 billion on national defense and defense-related activities. This is almost 30 percent of the annual budget. But it seems to me that we are also engaged in a current war, the war against disabling and killing diseases.

In 1982 fewer than 900 cases of AIDS had been reported. In 1983 there were 2,000 more cases. Last year, there were 4,000 new cases. You are projecting 9,000 new cases of AIDS in 1985; 73 percent of the patients diagnosed before January of 1983 have died. This is not a hypothetical threat of future hostilities. It is a present struggle with real casualties.

I view CDC as an essential part of this Nation's front-line defense in this war, and am therefore dismayed to find that your budget submission for CDC calls for a reduction of $18 million from the fiscal year 1985 appropriation level, with nearly every program area at or below the 1985 amount.

I am looking forward to your rationale for that cut. Please go ahead and proceed.

We will insert your statement in the record at this point.

[The statement follows:]

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STATEMENT OF DR. JAMES O. MASON

Mr. Chairman and Members of the Committee: It is a pleasure to be here today to support the FY 1986 budget request for the Disease Control, Research, and Training Appropriation, which is the principal source of funding for the Centers for Disease Control (CDC).

CDC is a scientific organization dedicated to developing and applying the technology needed to prevent unnecessary illness and premature death and to improving the health and quality of life of the American people. Through epidemiologic investigations, disease and risk factor surveillance, laboratory research, and behavioral science, we strive to provide valuable insight into the etiology of infectious diseases, chronic illnesses, and environmental and occupational health problems. We focus our resources on translating these findings into effective methods of preventing and controlling the illnesses and injuries that affect the health of children and adults.

I would like to take this opportunity to report to you on some of the recent benefits derived from the public investment in CDC. These highlights of our accomplishments illustrate not only some of our scientific abilities and achievements, but also the types of services we provide to our partners in public health--State and local health departments, other Federal agencies, schools of medicine and public health, health care providers, elementary and secondary schools, business and labor groups, and international health organizations.

Acquired Immunodeficiency Syndrome

During our Appropriations Hearing last February, we recounted that 3,452 cases of Acquired Immunodeficiency Syndrome (AIDS) and 1,488 deaths had been reported to CDC since June, 1981. As of our latest report (February 11, 1985), there have been 4,017 deaths and 8,314 reported cases, an increase of 140% in reported cases during the past year. We project that over 9,000 new cases could be reported in 1985, bringing the total number of cases to over 17,000 by the end of the year (CHART 1). The major risk groups continue to be homosexual or bisexual men, intravenous drug users, recently-arrived Haitians, and hemophiliacs (CHART 2); however, this disease may also be a threat to the general public. Although AIDS remains a serious public health problem which is increasing, several breakthroughs have occurred.

- The etiologic agent, a retrovirus called human T-lymphotropic virus type III (HTLV-III), has been identified. Specific antibodies have been isolated in more than 90% of AIDS patients and the prevalence of antibodies to HTLV-III has been determined in various studies of high risk groups. This confirms that several times more Americans in the high risk groups have already been infected with this virus than have manifested AIDS to date.

- A test has been developed to screen blood for the presence of antibodies to HLTV-III. In anticipation of the commercial availability of reagents for HTLV-III antibody testing, CDC is training laboratory personnel from State and local public

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health laboratories and blood and plasma collection facilities in correct use of the reagents. We are also training health department and community workers to provide appropriate information and education to individuals in high risk groups, including those found to be HLTV-III positive. In 1985, CDC will also be assisting State and local areas in developing and implementing new HTLV-III testing sites as alternatives to blood donation centers.

- Recommendations have been developed in consultation with the National Hemophilia Foundation for preventing transmission of AIDS to hemophiliacs through use of heat treated factor VIII concentrate.

Improving the Health of Children

Protection of children against infectious diseases and environmental hazards and education about healthy behaviors can have lifelong benefits. A broad array of CDC programs and studies have positive effects on child health. Several recent significant accomplishments are:

- Immunization levels for children entering school in 1983-84 were at an all time high: 98% protection against measles and rubella, and 97% for mumps, polio, and diphtheria, tetanus, and pertussis (DTP). Effective immunization and control programs resulted in record low numbers of cases of rubella, mumps, tetanus, polio, and diphtheria. No cases of diphtheria were reported in children under 15, and there has not been a wild virus case of polio in the United States since 1981. Only 2,534 cases of measles were reported in 1984. Although this is an increase from 1983, over 75% of the cases were from only 6 States and 94% of counties were measles-free for the entire year. We are also encouraging and promoting aggressive immunization efforts abroad as an indirect means of reducing imported measles in the U.S.

- In view of the fact that attendance at day care centers was shown to be a significant risk factor for several infectious diseases, CDC developed training materials for day care center directors to help them prevent transmission of infectious diseases among children attending day care, their families, and day care center workers. An estimated 20-50 percent of 2 to 3-year old children in day care centers contract giardiasis. About 25% of parents acquire the infection from their children. Prior to 1982, Cryptosporidia was unrecognized as a significant human parasite. In only a 7 month period in 1984, Cryptosporidia was identified as the cause of diarrhea in children in 6 day care centers in 5 different States.

- A large and comprehensive evaluation demonstrated that school health education has important beneficial effects on the knowledge, attitudes and practices of children. One specific example is the deterrence of cigarette smoking among seventh graders (CHART 3). In the comparison classrooms, 12.2% of seventh graders reported smoking, whereas only 7.7% of those who received health education reported that they smoke. If this health education curriculum were applied nationwide, we

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estimate that each year 146,000 7th graders would at least delay the onset of smoking. In addition to the effect on smoking behavior, the beneficial effects of school health education shown by this study encompass a broad spectrum of personal health habits.

- The associations, if any, between environmental exposures and health outcomes can be determined through epidemiologic and laboratory studies. In two studies of the potential effects of environmental exposures on children, one showed no association whereas the other revealed a problem. A case-control study of birth defects and military service in Vietnam found that veterans did not have an increased risk of fathering babies with defects. Vietnam veterans who had greater estimated opportunities for Agent Orange exposure did not seem to be at greater risk of fathering babies with defects when all types of serious structural defects are considered together. By contrast, analysis of data from the National Health and Nutrition Examination Survey (NHANES II) revealed strong associations between lead used in gasoline production and lead levels in people, including children. This information was used in the regulatory process by EPA to ensure marked reduction of lead in gasoline.

Improving the Health of Adults

The major health problems facing adults include infectious diseases as well as chronic diseases and injuries, many of which can be associated with occupational hazards or personal behaviors. Effective methods of preventing these illnesses and injuries range from use of vaccines to adoption of new engineering designs in the workplace to health promotion programs. Several examples of the benefits for adults derived from CDC programs are:

- Gonorrhea declined 6% in 1984 to fewer than 900,000 reported cases; and reported primary and secondary syphilis declined 11% in 1984, compared to a marginal increase of .1% from 1982 to 1983. The decline of syphilis in 1984 occurred in both males and females whereas females showed a slight increase in 1983. We are also making progress in addressing the other sexually transmitted diseases (STD) and syndromes. For example, chlamydia has replaced gonorrhea as the number one bacterial STD. Visits to private physicians for non-specific urethritis, a surrogate measure of chlamydia infection, have remained high, while those for gonorrhea declined (CHART 4). Tests have been approved which allow rapid diagnosis of chlamydia. Moreover, 32 States have initiated some chlamydia control activities, including reporting, testing, and counseling. Based on these results, we will be able to recommend chlamydia prevention and control strategies to the States.

- Adult immunizations are effective in preventing tetanus, diphtheria, measles, rubella, hepatitis B, influenza, and pneumococcal pneumonia. A study of pneumococcal pneumonia vaccine efficacy showed that persons with uncompromised health status had a vaccine efficacy of 60-70 percent, although the vaccine was less efficacious for persons with impaired immune status. The results of this study and others

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formed the basis for comprehensive recommendations on adult immunizations by our Immunizations Practices Advisory Committee. We have recently undertaken an Adult Immunization Initiative designed to improve immunization levels through increased public and private education and development of strategies targeted to specific risk groups. Working with professional and voluntary organizations and the vaccine manufacturers, we hope to achieve the same kind of success with immunization of adults that we have had with children.

- Twenty-four States were assisted by CDC in establishing surveillance systems for key health behaviors--smoking, obesity, uncontrolled hypertension, heavy drinking, lack of seat belt use, and sedentary lifestyle. A comparison of the results of surveys conducted in 1981-3 shows dramatic differences among the States (CHART 5). For example, the national estimate of the proportion of adults who smoke cigarettes is 31.2%; however, the prevalence by State ranges from 22% in Kansas to 37% in North Carolina. Similarly, the proportion of adults who do not use seat belts ranges from 42.5% in the District of Columbia to 72% in Arkansas. These State surveys provide valuable insights into State and regional differences and enable States to identify their own health problems and define their prevention priorities.

- The incidence of work-related injuries dropped to 7.5 per 100 fulltime workers in 1983, a significant reduction from the 1978 rate of 9.2 per 100 workers. CDC is working to accelerate this trend. In 1982 the National Institute for Occupational Safety and Health (NIOSH) began investigating individual fatal injuries at the worksite. Investigations under this program rose from 2 in the 1982 pilot program, to 8 during 1983, to 10 in 1984. Requests from business, labor, and government agencies for Health Hazard Evaluations and technical assistance also rose in FY 1984 to 563, an increase of 21% from 1983 (CHART 6). The results of these investigations are disseminated widely to industry and labor as well as to the Department of Labor. A good example of the relevancy of these reports is the recent incident in Bhopal, India. When the government of India requested assistance from CDC in assessing the health effects of exposure to methyl isocyanate, NIOSH provided four Criteria Documents which were used as technical resources for CDC staff who conducted this assessment.

Domestic and International Investigations

CDC maintains the scientific expertise needed to resolve outbreaks of unknown origin and to detect similar events occurring in several States. For example, we provided assistance to the Minnesota Department of Health in determining that an outbreak of chronic diarrhea was associated with raw milk consumption. Similar outbreaks are suspected in other States. Laboratory research to identify the etiologic agent continues. In 1984, 40 epidemiologists assigned by CDC to State and local health departments completed over 700 investigations of health problems. CDC also provided epidemiologic aid in response to 23 international emergencies in FY 1984. For example, CDC is actively involved in famine assessment in Subsaharan Africa, in

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cooperation with the Department of State, the U.S. Agency for International Development, and other international agencies.

Budget Request

These accomplishments are just a sample of the diverse research projects and programs managed by CDC. The President's FY 1986 Budget assures that we have the personnel, equipment, and facilities needed to remain on the cutting edge in new areas of prevention while maintaining basic disease control programs and the ability to respond to rare occurrences of a broad range of preventable health problems.

Our budget request for FY 1986 is $392.1 million, which includes an increase of $5.5 million to provide scientific equipment for the new virology laboratory to be completed in 1987. We are also requesting 3,799 FTE's, which excludes Reimbursable and Trust Fund FTE's. For AIDS activities, we are requesting $18.7 million to continue support for epidemiologic studies of high risk groups, laboratory research and training, surveillance through State and local health departments in high incidence areas, health information and education activities, and for development of control methods. This amount together with funds for other PHS-supported AIDS activities totals $85.6 million in the President's FY 1986 Budget.

Grants to States for the Preventive Health and Health Services Block Grant, Immunization, and Sexually Transmitted Disease Control will be maintained at the current level. The request does not include funds for diabetes projects in States and the occupational safety and health training grants because these projects are completed. Funds from the Preventive Health and Health Services Block Grant will continue to be available for control of tuberculosis, which decreased by 9% in 1984.

A savings of $466,000 in budget authority is anticipated as a result of charging GAO-recommended user fees for private clinical laboratories participating in the U.S. proficiency testing program and for reference reagents distributed to commercial manufacturers. The request also includes a reduction of $4.9 million for the proposed 5% pay cut and a decrease of $1.3 million as a result of the 10% reduction in administrative expenses.

I would be happy to answer any questions from Members of the Committee.

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CHART 1

Projections of AIDS Cases Reported to CDC, by Quarter of Diagnosis

United States, December 31, 1984

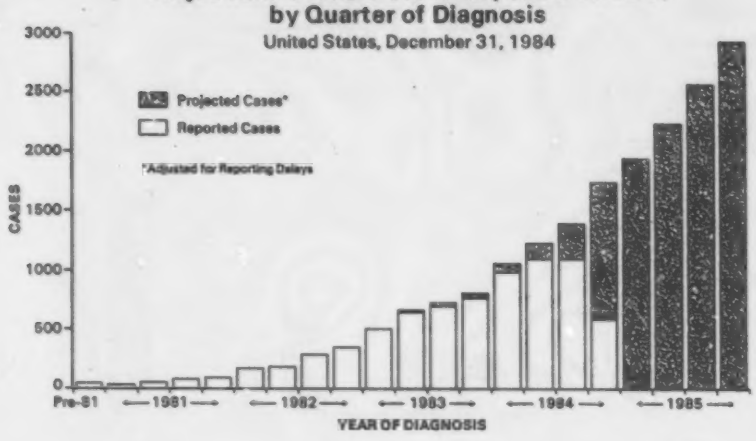

CHART 2

Overlap of Adult Groups at Increased Risk for AIDS

United States, December 31, 1984

N=7609

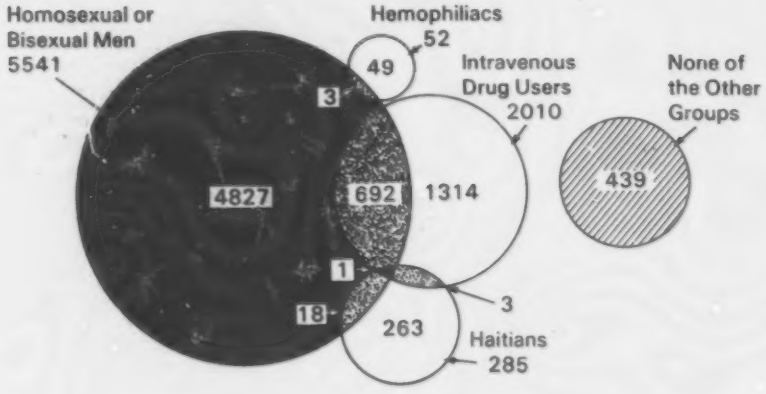

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CHART 3

Comprehensive School Health Education Makes a Difference

Estimates of Number of Children Who Smoke

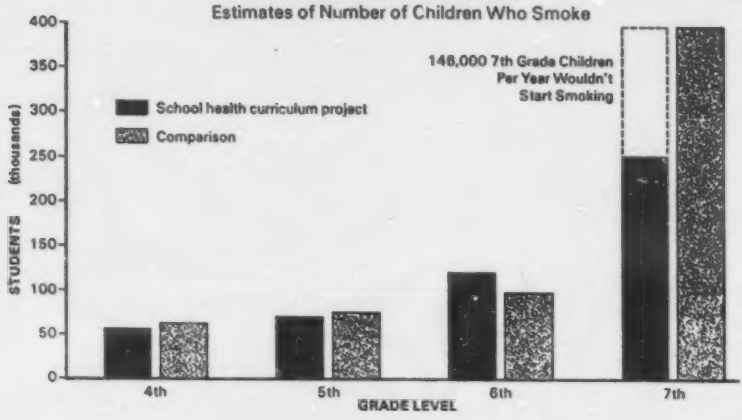

CHART 4

Non-Specific Urethritis and Gonorrhea For Males

Number of Visits to Private Physician's Office
United States, 1966-1983

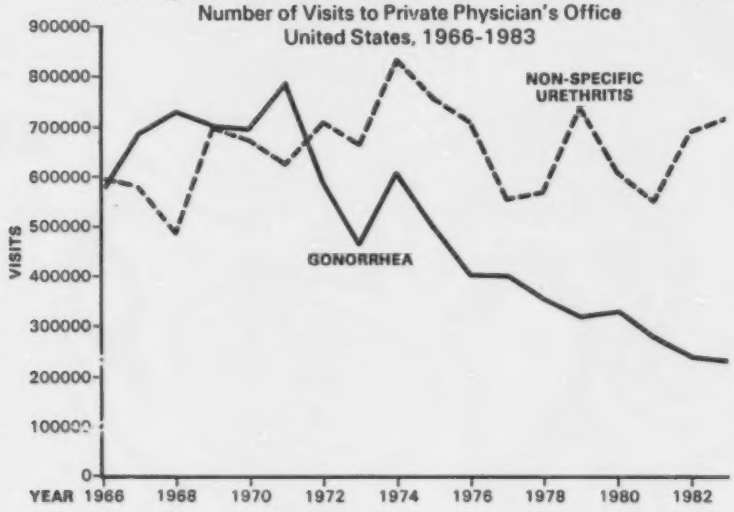

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CHART 5

Range of State-Specific Risk Factor Rates

Behavioral Risk Factor Surveillance 1981 -- 1983

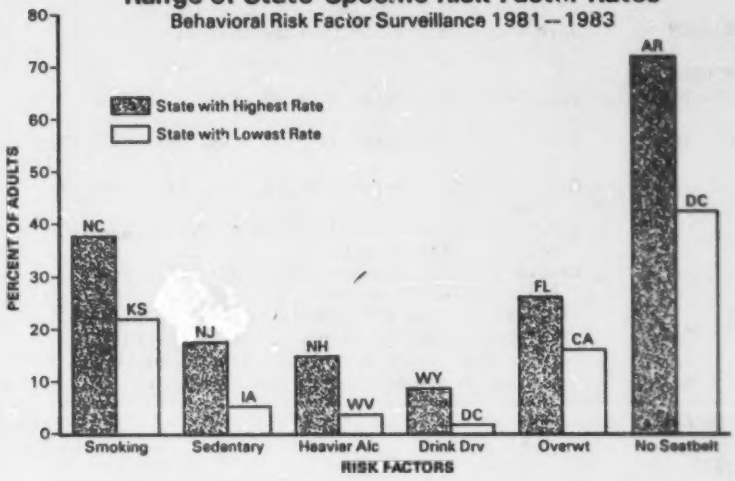
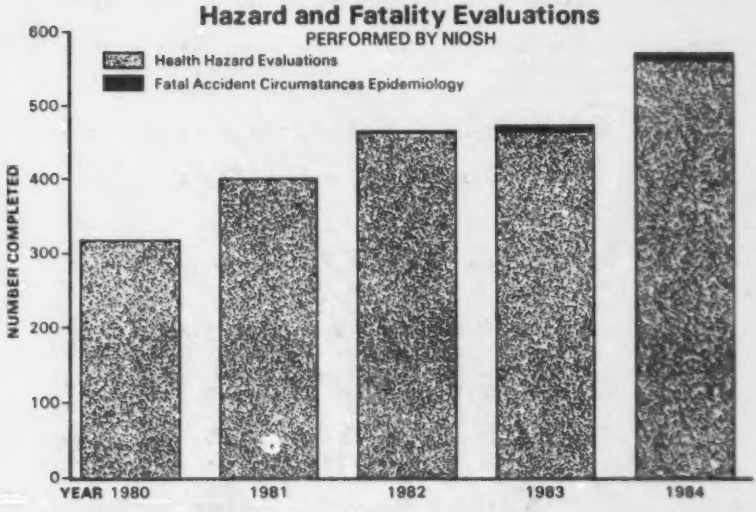


CHART 6

Hazard and Fatality Evaluations

PERFORMED BY NIOSH



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Biography of Dr. James O. Mason

POSITION	:	Director, Centers for Disease Control
BIRTHPLACE AND DATE	:	Salt Lake City, Utah, June 19, 1930
EDUCATION	:	B.A. - 1954, University of Utah, Salt Lake City, Utah M.D. - 1958, University of Utah, Salt Lake City, Utah M.P.H. - 1963, Harvard School of Public Health, Boston, Massachusetts Dr.P.H.- 1967, Harvard School of Public Health, Boston, Massachusetts Internship, 1958-1959, Johns Hopkins Hospital, Baltimore, Md. Residency, Internal Medicine, 1961-1962, Peter Bent Brigham Hospital, Harvard Medical Service, Boston, Massachusetts
EXPERIENCE	:	
1983-Present	:	Director, Centers for Disease Control
1979-1983	:	Executive Director, Utah Department of Health
1978-1979	:	Associate Professor and Chairman, Division of Medicine, Department of Family and Community Medicine, University of Utah College of Medicine
1976-1978	:	Deputy Director of Health, Utah Division of Health
1970-1976	:	Commissioner, Health Services Corporation, The Church of Jesus Christ of Latter-day Saints
1969-1970	:	Deputy Director, Centers for Disease Control (CDC), DHEW, Atlanta, Georgia
1968-1969	:	Chief, Infectious Diseases, Latter-day Saints Hospital and Assistant Professor, Department of Medicine and Preventive Medicine, University of Utah, College of Medicine
1964-1968	:	Deputy Director, Bureau of Laboratories, Centers for Disease Control (CDC) DHEW, Atlanta, Georgia
1961	:	Chief, Surveillance Section, Epidemiology Branch, Center for Disease Control (CDC), DHEW, Atlanta, Georgia,
1960	:	Chief, Hepatitis Surveillance Unit, Epidemiology Branch, CDC, Atlanta, Georgia
1959	:	Chief, Epidemic Intelligence Service, CDC, Atlanta, Georgia

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TEACHING APPOINTMENTS : Clinical Professor, Department of Family and Community Medicine, University of Utah College of Medicine, May 1, 1979 to December 1983

Clinical Professor, Department of Pathology, University of Utah College of Medicine, May, 1980 to December, 1983

ASSOCIATION MEMBERSHIP : Chairman, Utah Governor's Advisory Committee for Comprehensive Health Planning, 1975 to 1977

Chairman, Joint Residency Committee in Preventive Medicine and Public Health University of Utah College of Medicine, 1975 to 1980 Member, Utah Cancer Registry Research Advisory Committee, 1976 to 1983

Chairman of Board, Hospital Cooperative of Utah, July, 1977 to 1979 Chairman, Utah Health Planning and Resource Development Advisory Group Executive Committee 1977 to 1979

Member, twenty-two other committees or organizations

HONORS : Alpha Epsilon Delta, University of Utah 1954

Phi Kappa Phi, University of Utah, 1956

Alpha Omega Alpha, University of Utah, 1957

Roche Award, University of Utah, 1957

Wintrobe Award, University of Utah, 1958

Delta Omega, Harvard University, 1963

Distinguished Alumni Award, University of Utah, 1973

Beatty Award, Utah Public Health Association 1979

Administrator of the Year Award, Brigham Young University, 1980

Sigma XI, CDC. Atlanta, 1964

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INTRODUCTION OF ASSOCIATES

Dr. MASON. Thank you, Chairman Weicker, Senator Byrd, and Senator Andrews. We are delighted to have this opportunity to be here today, appearing before you.

I have with me, Mr. William E. Muldoon, Director, Office of Program Support, and Mr. William Beldon, Branch Chief, Office of Budget, Office of the Secretary of Health and Human Services.

PROGRAM HIGHLIGHTS

We have submitted our prepared testimony, so I will simply summarize a few highlights.

It is a pleasure to be here today to support the fiscal year 1986 budget request for the disease control research and training appropriation, which is the principal source of funding for the Centers for Disease Control. I would like to take this opportunity to report to you on some of the recent benefits derived from the public investment in CDC.

You have already mentioned AIDS, and if we could see the first chart. As of March 25, 1985, 8,945 cases had been reported, and 4,315 deaths. The number of cases is an increase of 160 percent during the past year. As you have mentioned, we project over 9,000 new cases during the year 1985. This simply gives the projections that you have already referred to.

During the past year, since we reported to you, the combined efforts of the Public Health Service and academia have resulted in the identification of the etiologic agent that is responsible for this disease. A test has been developed and is now being applied in our blood banks to protect the Nation's blood supply. Recommendations have been made so that we can make the factor H, which is given to hemophiliacs, safe so that it no longer transmits the virus.

Public education has been conducted throughout the Nation as we attempt to control this disease.

During the past year since we reported to you, the major risk groups have remained pretty well stable. Those groups that were identified in the past, homosexual or bisexual men, intravenous drug abusers, and Haitians still comprise the major groups that are afflicted with this problem.

Now, leaving AIDS, just a word about immunization. Immunization levels are at an all time high; 98 percent for school children for measles and rubella, and almost 98 percent for mumps, polio, diphtheria, tetanus, and pertussis.

In the field of sexually transmitted diseases, for the first time, fewer than 900,000 cases of gonorrhea have been reported. Primary and secondary syphilis declined 11 percent in 1984.

The next chart please. Visits to physicians for nonspecific urethritis remain high, and these are largely the chlamydia infections that have been identified, where we feel that nationwide there are probably more than 3 million cases a year.

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During the past year, two tests have been approved by FDA to use in the diagnosis of chlamydia infections. The first drug, oral acyclovir for the treatment of genital herpes was approved and is now available on the market.

We have also come to the conclusion that adult immunizations are highly effective in preventing tetanus, diphtheria, measles, rubella, hepatitis B, influenza, and pneumococcal pneumonia.

We are doing surveys in terms of risk factors that exist in the Nation today, and the next chart shows surveys that are being conducted in most of the States. This illustrates, for example, that with regard to smoking, the national average of the adults in our Nation who use tobacco, is 31.2 percent, but ranges from a low of 22 percent in Kansas to 37 percent in North Carolina. Such statistics on risk factors can be used at the State and local levels to target specific programs to reduce the incidence of illness.

In the field of occupational safety and health, the incidence of work related injuries was 7.5 per 100 full-time workers in 1983, a significant reduction from the 1978 rate of 9.2 per 100 workers. We are working at the present time to accelerate that trend.

In 1982, the National Institute for Occupational Safety and Health began investigating individual fatal injuries at the work site. This is carried out at our laboratory in Morgantown, WV. Investigations under this program rose from 2 in the 1982 pilot program to 8 in 1983 and 10 in 1984.

Requests from business, labor, and government agencies, for health hazard evaluations and technical assistance rose in fiscal year 1984 to 563, an increase of 21 percent from 1983.

We continue to maintain scientific expertise to provide epidemic assistance worldwide. Our 1986 budget request includes an increase for equipping the new virology laboratory, and program decreases for the education and research centers, diabetes State projects, and TB grants. Other grants to States are requested at the 1985 level. The budget includes $18,700,000 for AIDS, which is the same as 1985, and the budget includes proposed user fees for proficiency testing and reagents furnished to private manufacturers.

I will be happy to now answer any questions.

BUDGET REDUCTIONS

Senator WEICKER. I am going to turn the questioning over to Senator Byrd, but I have one brief question.

The $18 million cut, was that medical or budgetary?

Dr. MASON. The reductions?

Senator WEICKER. You have it categorized, "the overall $18 million cut." Is that medical or is that budgetary? Was it occasioned by improving situations in the various areas that you cover, therefore, you don't need the money, or was it a part of this overall drive to cut the Federal deficit?

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Dr. MASON. There are reductions in areas where the work is largely completed, such as the diabetes demonstration grants, and in the Tuberculosis Grant Program where the work is accelerating, and it is felt that they can continue without further funding in that area.

Senator WEICKER. I will come back to this. I know that Senator Byrd has a busy schedule, so I will let him now proceed.

CHEMICAL PLANTS

Senator BYRD. Mr. Chairman, I thank you.

I ask unanimous consent that my statement and question, which will not consume more than 5 minutes, appear after any further statement and questions of the chairman.

Dr. Mason, you referred to the ALOSH, the Appalachian Laboratory on Occupational Safety and Health in Morgantown. That facility specializes in respiratory research, and has a very good record, I think, in developing the testing devices and methods for the protection of the coal miners. Their reputation is such that I understand that the Department of the Air Force and the Army are currently exploring cooperative research on respirators and related work there at Morgantown.

I have one matter which I would like to discuss for the record at this moment, and that concerns the health and safety of the people in the Charleston area, the Kanawha Valley, WV.

As you may be aware, there are more than 20 chemical plants located in this valley. It is a great chemical complex. These plants have made the Charleston area very prosperous. But as we learned from the tragedy that occurred in Bhopal, India, it is important that the people in the surrounding communities be adequately protected from the potential, although highly unlikely, I would say, hazards from these plants.

At my request, both the Environmental Protection Agency and the Occupational Safety and Health Administration have reviewed the operation of the Union Carbide plant in Institute, WV, which is the sister plant to the India plant, and which is the only remaining plant in the world, as I understand it, that makes the chemicals that were involved in the India plants.

I am not sure that there is adequate coordination among the Federal agencies that have jurisdiction in this matter. I want to be certain as I can be that all reasonable measures are being taken to protect the lives of the citizens of the Kanawha Valley.

The State of West Virginia and the people of the Kanawha Valley have recently formed the National Institute for Chemical Studies, and I believe that that institute would help focus scientific research on the issues relating to the protection, transportation, and use of potentially hazardous chemicals in a safe manner. So the people of West Virginia are trying to help themselves.

Given the expertise that exists within the ALOSH facility in Morgantown and elsewhere in NIOSH and the Centers for Disease Control, I would very much appreciate a report from you making suggestions on the following three points. You may wish to comment on them briefly now, or you may not.

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One, suggestions for improving the safety of the people in the Kanawha Valley;

Two, any additional research which should be performed to better understand the nature and effects of these chemicals; and

Three, suggestions that would approve coordination among Federal agencies with jurisdiction over the chemical industry.

I recognize that this is going to take some time, but I wonder if it would be possible for me to have a response from you within, say, 45 days.

Dr. MASON. Senator Byrd, I don't see any problem in our responding within 45 days on those three items that you have outlined.

Senator BYRD. Thank you.

I would like to ask that all possible cooperation be provided to this newly formed National Institute for Chemical Studies in the Kanawha Valley. I will follow this in writing, and perhaps, if you feel that it would be appropriate and helpful, I could possibly put you in touch with some of the individuals who are on the board of this National Institute. It could be that there might be some help rendered by way of cooperation, particularly with the ongoing laboratory research that is occurring in Morgantown.

Would you wish to comment on that?

Dr. MASON. I would be very pleased to have the name of individuals that we might contact and work with. Just as an aside, when the Bhopal problem occurred in India, within 2 or 3 days, the Government of India contacted CDC through our State Department and requested that we immediately dispatch a team there. Representatives of NIOSH, our Center for Environmental Health, and our Assistant Director for Public Health Practice, plus a specialist from Johns Hopkins University, immediately left for India.

We were pleased that we had the confidence of that nation, and, second, to have the opportunity to observe the problem in Bhopal firsthand so that what we were able to learn from that experience could be brought back and applied where applicable in our own settings here in the United States. So we have a deep interest.

The bottom line for CDC is prevention, not trying to clean up after the disaster has occurred. We are active in this area. We are interested. We would be delighted to respond to questions that you have given us.

PREPARED STATEMENT

Senator BYRD. Thank you, Dr. Mason. I will be in further touch with you.

Thank you, Mr. Chairman.

[The statement follows:]

STATEMENT OF SENATOR ROBERT C. BYRD

Dr. Mason, I have a few questions relating to the National Institute for Occupational Safety and Health, NIOSH, which I believe is under your jurisdiction, and I am particularly interested in the work of the Appalachian Laboratory on Occupational Safety and Health which is located in Morgantown, WV.

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The Morgantown facility specializes in respiratory research and has an outstanding record in developing testing devices and methods for the protection of the American miner. Their reputation is such that I understand that the Departments of the Air Force and Army are currently exploring cooperative research on respirators and related work with the ALOSH personnel. Let me indicate now my support for those cooperative efforts.

I have one very important matter which I would like to discuss with you; and this concerns the health and safety of the people of Kanawha Valley, WV. As you may be aware, there are more than 20 major chemical manufacturing plants in this valley around Charleston, WV. These plants have made Charleston the most prosperous area of my State; but as we learned from the tragedy which occurred in Bhopal, India, this past December, it is vitally important that the people in the surrounding communities be adequately protected from the potential, though unlikely, hazards from these plants. At my request, both the Environmental Protection Agency and the Occupational Safety and Health Administration have reviewed the operation of the Union Carbide plant in Institute, WV, which is the sister plant of the one located in Bhopal, India. However, I am still not convinced that there is adequate coordination among the Federal agencies that have jurisdiction in this matter. I want to be certain that all reasonable measures are being taken to protect the lives of the citizens of the Kanawha Valley.

The State of West Virginia and the people of Kanawha Valley have recently formed the National Institute for Chemical Studies, of which I am proud to be a member of the board; and I believe that this Institute will help focus scientific research on the issues relating to the protection, transportation, and use of potentially hazardous chemicals in a safe manner. So, the people of West Virginia are trying to help themselves.

Dr. Mason, given the expertise that exists within the ALOSH facility in Morgantown and elsewhere in NIOSH and the Centers for Disease Control, I would very much appreciate a report from you making suggestions on the following three points:

1. Suggestions for improving the safety of the people in the Kanawha Valley;
2. Any additional research which should be performed to better understand the nature and effects of these chemicals, and
3. Suggestions that would approve coordination among Federal agencies with jurisdiction over the chemical industry.

I recognize this may present a short time constraint, but may I have your response within 45 days?

Also, may I ask that you provide all possible cooperation to the newly formed National Institute for Chemical Studies in the Kanawha Valley.

AIDS FUNDING

Senator WEICKER. Thank you, Senator Byrd. I think your concern over this situation is well placed. I hope, just as Dr. Mason said, the time to get a hold of this thing is now, not when any tragedy occurs. It seems to be a very farsighted view that you take. Certainly any way that the subcommittee can be helpful to assist Senator Byrd's wishes in this matter, all you have to do is call the staff.

Dr. MASON. Wonderful. We will be delighted to do that. Thank you, Mr. Chairman.

Senator BYRD. Thank you very much.

Senator WEICKER. Let's get on to the other matters.

In each of the past 4 years it has been necessary for the Congress to provide a supplemental appropriation for AIDS activities in addition to the amounts provided through regular appropriation bills.

Is the fiscal year 1986 amount that you are requesting for AIDS, $18.7 million, which is the same as the fiscal year 1985 appropriation, going to be sufficient for the range of laboratory investigations, surveillance, epidemiological studies, prevention control projects, et cetera, in

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light of the increasing incidence of the disease, or will we again be facing a supplemental or a reprogramming request for AIDS in fiscal year 1986?

Dr. MASON. At the present time, we are reviewing the entire situation. As you said, this is a rapidly moving problem. As time goes on, we are more aware of the total extent of AIDS and right now we are reassessing where we stand. I am sure you have heard of alternative testing sites to protect the blood supply. At the Secretary's request, we are making plans so that money can be diverted to the States to assist them with these alternative testing sites.

The Secretary has asked us to look at those costs, and come to her so that appropriate recommendations can be made at the appropriate time for additional funds. The philosophy of the Secretary has been that, before we know what we are dealing with, don't put out pie-in-the-sky requests, but evaluate carefully where the needs are, and then she would be very sympathetic to any requests for additional funds that may be needed.

AIDS INCIDENCE

Senator WEICKER. If you extrapolate the figures for the past 3 years as to the incidence of AIDS, it seems to me that it wouldn't be very long before you would have the entire population of the United States involved.

Dr. MASON. Rarely, with an epidemic, can you extrapolate for an unlimited time. We can only do our forecast a few years ahead. I do not think that the entire population of the United States is at risk, but that doesn't mean that we don't want to take whatever control steps are necessary because we want to circumscribe this epidemic just as rapidly and completely just as soon as we can.

AIDS CONTROL

Senator WEICKER. Are you confident that you are going to be able to get this in hand in the sense of having identified the cause of it? Is that part of the attitude that is out there now as far as the medical community is concerned?

Dr. MASON. Chairman Weicker, our main concerns with AIDS, even though we have identified the agent and have a test that enables us to do better studies, is to identify those at risk. But at the present time, we are very limited in terms of our control ability. We don't have a vaccine. We are working, along with FDA and the National Institutes of Health, to develop a vaccine as quickly as possible. We don't have any therapy for the disease. We wish we had a magic bullet, like a shot of penicillin, or something else that would control this disease, or cure it.

Our main tools at this point in time are education and information, so that people can make choices which will enable them to either avoid transmitting the infection, if they are already infected, or avoid the circumstances whereby infection may be transmitted to them, if they are not already infected.

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The tools that we have today are not the strong tools of vaccine prevention, or treatment prevention, but education and information.

AIDS VACCINE DEVELOPMENT

Senator WEICKER. These are in terms of a learning process for me. I don't mean to badger you on this point, nor am I, I might add, feigning ignorance. There is ignorance on my part.

With what you know now about AIDS, with whatever tests you have in hand at this juncture, what can you expect in terms of time vis-a-vis a vaccine if, indeed, you took the AIDS experience and compared it to some other infections—I will allow you to draw whatever analogy you want. What do you expect as to the state of knowledge now, as to when you are going to be able to get a handle on it?

Dr. MASON. It is very hard to compare AIDS with any other disease. To give you an illustration, after polio was recognized, and the virus isolated, it still took a fair length of time. I am talking about years, before we had both the oral polio vaccine and the killed polio vaccine.

Senator WEICKER. When you say, years, what was involved there?

Dr. MASON. Probably we are talking about a timespan of 15 or 16 years.

With hepatitis B, with better technology, the time for the identification of the agent, and the production of the vaccine was shorter, 7 or 8 years. If one extrapolated that to AIDS, with the new technology, you would hope that something would become available much more rapidly than the time it took for polio or hepatitis B.

To be very frank with you, we are dealing with a retrovirus, a group of agents that don't behave necessarily——

Senator WEICKER. What is a retrovirus?

Dr. MASON. It is a type of a virus that, instead of possessing DNA characteristics, it has RNA. It is a very complex shift in the relationship of the molecular structure of this virus. It is from a group of viruses that we know a little less about than some of the viruses that have been isolated in the past, and dealing with them, in terms of vaccine preparation, is turning out to be somewhat difficult. That is why it is very, very hard to predict how long it will take to come up with a vaccine.

At the National Institutes of Health, everything possible is being done to come up with a vaccine, but to predict at what point in time vaccine will become available on the market and licensed, I wouldn't want to mislead you by saying 2 years, 5 years, or 10 years. I just don't believe we know at this time.

AIDS FINANCIAL CONSTRAINTS

Senator WEICKER. My last question, before I turn the questioning over to Senator Inouye. Is there any financial constraint that you see by virtue of the requests that are being made insofar as AIDS is concerned? Obviously, you have a grasp of not only your own budget, but the other areas of activity where Federal funds are being used.

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Dr. MASON. Within the Public Health Service, we are now looking at our budgetary needs. We recognize that this Nation wants to make optimal progress in the understanding and the control of this disease. In this rapidly moving area, we are evaluating resources in all of the agencies within PHS, including CDC, at the present time. The Secretary has directed us to do so, and to let her know if monetary means are slowing down our progress in development of vaccines, therapy, or control technology at the State and local levels.

Senator WEICKER. Senator Inouye.

Senator INOUYE. Thank you, Mr. Chairman, but I have no questions. I would like to submit some for response by the agency.

Senator WEICKER. Thank you very much, Senator Inouye. Your questions will be placed in the record, and submitted to the agency.

Senator INOUYE. Thank you, Mr. Chairman.

TUBERCULOSIS

Senator WEICKER. I am going to have a couple more questions and then my good friend Senator Inouye will Chair the committee until Senator Proxmire arrives at 11 o'clock.

In 1984, there were more than 21,000 cases of tuberculosis reported in the United States, a number of which were resistant to drugs. In view of this number, and the danger inherent in the spread of drug resistant tuberculosis, how can CDC justify the elimination of its tuberculosis grants program?

Dr. MASON. As you know, this has come up over a number of years. It has been the position of the administration that in those areas where we are making the kind of progress that needs to be made to meet the target objectives of the Nation, or where the States have learned what they need to do to decrease or control the disease, funding would no longer be requested. We feel that we will meet our targets without Federal funding.

TUBERCULOSIS AND CHILDREN

Senator WEICKER. What is the incidence of reported cases of tuberculosis in children?

Dr. MASON. About 6 percent of the 23,000 cases in 1983 were childhood related cases.

Senator WEICKER. Is this incidence on the rise?

Dr. MASON. We were having increased numbers of cases during the influx of South East Asian refugees. Since we are doing more at the entry level to screen those cases, to identify them, and get them under treatment before they come into the United States, we are now showing a decrease, not only in total cases, but in our childhood related cases.

There was a momentary blip in those years when we had a lot of Asian refugees.

Senator WEICKER. My friend Senator Inouye is here, and when I visited certain education and sanitary facilities in Hawaii last year, it came to my attention that Hawaii, in effect, is performing the same

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function as, let's say, New York did during the immigration of the Europeans to the shores of the United States. This is either posing or could pose many problems in the area, just this tuberculosis situation. Is that a problem in the Pacific Basin and, more particularly, to the extent that those people come to the United States through the gateway of Hawaii?

Dr. MASON. Yes; the incidence of infectious tuberculosis is higher in most of the South East Asian countries that have been the source of those refugees. Therefore, we have now put into place a very specific screening program before they come to the continental United States or Hawaii. We try to identify those cases prior to their arrival. If they are positive for tuberculosis, we try to introduce therapy so that they arrive here with their disease at a noninfectious stage. The local health departments, at that point, are alerted to their circumstances, the need for followup, and the need to continue to see that they get the necessary treatment.

For a while, a number of years ago, they just came to this country and the local health departments had to find them, identify them, and diagnose them after they arrived here. I think that we are now doing a much better job because we know what their status is before they arrive in the United States.

DTP VACCINE SUPPLY

Senator WEICKER. My last question, and then the other questions I will go ahead and submit for the record, is the adequacy of the DTP vaccine supply. The administration has proposed to freeze immunization programs to the fiscal year 1985 level, but serious problems exist with the diphtheria-tetanus-pertussis vaccine. Its cost has increased from 11 cents per dose in 1982, to $2.80 per dose today. There is only one company in the United States willing to distribute the vaccine. Spot shortages have already occurred, and there is no DTP vaccine in the CDC vaccine stockpile.

Specifically, what is CDC doing to ease prodution and distribution problems of the DTP vaccine, and how can those problems be addressed without any increase in funds?

Dr. MASON. CDC traditionally has not been a purchaser of DTP vaccine. CDC, in its categorical grant for immunization, by agreement with the States, provided the viral vaccines, measles, mumps, and rubella, and the polio vaccine. The States, from their funds, purchased DTP vaccine.

Last year, as the price began to go up, Congress appropriated $8 million so that we could begin to assist the States with the much increased costs for that vaccine. The shortage developed at about the same time we were trying to buy DTP vaccine for the stockpile. At the present time, we have promulgated recommendations, because of the shortage, so that instead of five doses being given, we are only giving the initial three doses, and we are withholding the doses normally given at 18 months and 4 to 6 years. As soon as this period of shortage is over, and

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we predict that this will occur later in this calendar year, then pediatricians and general practitioners, who are responsible for immunizing children, will immunize those children that were deferred from the program.

I think that the States and local governments are going to have to dig deeper into their pockets because of the increased cost. The appropriations we have will certainly buy fewer doses as a result of the cost increase.

Senator WEICKER. Are these children at risk during this postponement?

Dr. MASON. The increased risk is minimal. The initial primary series of DTP is to get their antibody levels up, and then the booster doses are to protect them so that once up, they will go through the rest of their childhood and adolescent years with adequate protection. It is optimal to get the fourth and fifth doses, but under the circumstances of the shortage, we try to cut back in the area where the children would be least at risk.

Senator WEICKER. Are you telling me, therefore, that even with more money, there is no way that this is going to produce more vaccine at this time because of manufacturing limitations?

Dr. MASON. Not immediately because right now, even though we have had an RFP out to buy DTP vaccine, it just isn't available. Everything that is being produced and distributed is going immediately into the private and public sectors so that at least the children get their first three doses.

We would hope that as we get further into this fiscal year, and supplies begin to catch up, we will be able to put vaccine away for the stockpile.

The shortage was not only because we went rapidly from three suppliers to one supplier, but one of the suppliers also had some difficulties with two lots. When both of these things occurred simultaneously, a shortage occurred. We had a number of variables all going bad simultaneously. We would like to have a 6-month stockpile of all childhood vaccines, so that if manufacturers drop out, if a lot, for one reason or another, doesn't meet the high standards that are required in this country, that we don't run into shortage problems again.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I thank you very much, and I now turn the Chair over to Senator Inouye.

The questions referred to earlier will be inserted in the record at this point.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

AIDS/SUFFICIENT FUNDING

Question: In each of the past four years, it has been necessary for the Congress to provide a supplemental appropriation for AIDS activities, in addition to the amounts provided through regular appropriations bills. Is the FY 1986 amount you are requesting for AIDS, $18.7 million, which is the same as the FY 1985 appropriation, going to be sufficient for the range of laboratory investigations, surveillance, epidemiological studies, prevention and control projects, etc. in light of the increasing incidence of this disease?

Answer: The AIDS problem is constantly changing. The Secretary has directed that all agencies within the Public Health Service evaluate AIDS resource requirements. We are to advise her of any monetary problems that are slowing down progress in the development of vaccines, therapy, or control technology.

Question: Will we again be facing a supplemental or reprogramming request for AIDS for FY 1986?

Answer: The evaluation of resource need we are currently doing will provide the answer for FY 1986 also. However, at this time, we believe the FY 1986 budget request for AIDS is sufficient.

Question: Is it true that for FY 1985, Secretary Heckler plans to submit to the Congress a reprogramming of up to $12 million from already appropriated funds for alternate site blood screening tests for separating potentially contaminated blood from uncontaminated blood?

Answer: Yes, the Department will request that $10.4 million be reprogrammed for this purpose.

Question: From what existing programs would these funds be taken?

Answer: The request proposes to reprogram: $1.5 million from uncommitted STD grant funds; $3.65 million available by providing various CDC contracts scheduled for renewal during the last quarter of 1985 with just a two- to three-month extension from 1985 appropriations, with the plan to finance full-year continuation awards in the first quarter of 1986; $0.25 million by deferring CDC scientific equipment purchases for a few months and $5 million from unobligated National Health Service Corps funds.

Question: Why was this blood screening proposal not part of your 1985 budget so that funds need not be diverted from other programs?

Answer: We did not know enough about the AIDS problem at the time the FY 1985 budget was prepared to predict and budget for this blood screening proposal. The AIDS blood screening tests were not ready for marketing approval by the Food and Drug Administration until early in 1985, long after the FY 1985 budget was developed.

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AIDS/THREAT TO GENERAL PUBLIC

Question: Your testimony mentions the severity of the AIDS problem as it poses a growing threat to the general public, in addition to the more common at-risk groups (i.e. homosexuals, bisexual men, intravenous drug users, hemophiliacs and certain Haitians). Why is it that AIDS is becoming such a growing threat to the general population?

Answer: The "general population" could be at risk for AIDS through two potential routes of HTLV-III virus transmission. The first route would be the transfusion of infected blood or blood components. With the implementation of HTLV-III antibody testing in blood banks and plasma centers, the risk of transfusion-associated AIDS is expected to decrease, not increase. The other route of transmission would be through sexual contact with an infected person. As the number of infected persons increases, so does the possibility of such transmission.

Question: What prevention programs are underway or being planned to stem this most serious health threat?

Answer: CDC has provided AIDS risk reduction information through various means including regular updates and prevention recommendations in the Morbidity and Mortality Weekly Report (MMWR). In addition, funds have been provided to assist health departments and community organizations to provide prevention/risk reduction information to AIDS patients, individuals with AIDS-related conditions, other individuals at increased risk for AIDS, and the general public. In February and March 1985, CDC provided funds to the six States/cities with the highest number of AIDS cases and to the U.S. Conference of Mayors for these purposes. Additional educational efforts are underway to train health department and other personnel to counsel individuals to reduce risks of acquiring and transmitting the AIDS virus. Current prevention efforts will need more evaluation to identify those methods and activities that are most effective. CDC will take an active role in this evaluation and in encouraging State and local areas to adopt and implement education/risk-reduction methods that are most cost-beneficial. Work is also underway in the National Institutes of Health and the Food and Drug Administration to develop treatments and preventive vaccines for AIDS.

BLOOD TEST TO DETECT AIDS ANTIBODIES

Question: In April 1984, Secretary Heckler announced that a blood test for AIDS would be available within six months that would "identify AIDS victims with essentially 100 percent certainty" and prevent transfusion-related AIDS, including AIDS in hemophiliacs. The Office of Technology Assessment, in a report issued last month, claims that the announcement "may have impeded the generation and dissemination of new information about AIDS" because it was not accurate as to the test's usefulness or availability, and that it prematurely committed the federal government to require use of the test in blood plasma collections. Do you agree with this assessment?

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Answer: The two ELISA tests for antibody to HTLV-III licensed during March 1985 have a slightly different sensitivity (the ability of a test to correctly identify a person who is infected) and specificity (the ability of a test to correctly identify a person who is not infected). The sensitivity for the tests is 94%-99% and the specificity for both is 99% or higher. Preliminary information about HTLV-III antibody tests from research conducted during 1983 and early 1984 suggested the tests would be useful to screen donated blood and plasma. The Department is committed to the goal of achieving a safer blood supply through the development, evaluation, and marketing of these tests.

Question: What is your current opinion of the test's value?

Answer: The role of the HTLV-III antibody tests in screening donated blood and plasma and in assessing the clinical status of people who may have been infected with HTLV-III is being defined. CDC, NIH, and FDA in conjunction with blood banks are evaluating the significance of donors found to have antibody and assessing the role of the screening test in blood and plasma collection programs. Other research studies are defining the role for the test in clinical evaluation of people who may have been exposed to HTLV-III or who are at risk of AIDS.

ADEQUACY OF DTP VACCINE SUPPLY

Question: The Administration has proposed to freeze immunization programs at the FY 1985 Level. But serious problems exist with the diphtheria-tetanus-pertussis (DTP) vaccine:

-- Its cost has increased from 11 cents per dose in 1982 to $2.80 per dose today;

-- There is only one company in the United States currently willing to distribute the vaccine;

-- Spot shortages of the vaccine have already occurred;

-- There is no DTP vaccine in the CDC vaccine stockpile.

Specifically, what is CDC doing to ease production and distribution problems of the DTP vaccine, and how can these problems be addressed without any increase in funds?

Answer: First of all, the current situation of spot shortages of DTP vaccines is not due to a lack of adequate funds for vaccine purchases. The DTP shortage is due to the fact that, 2 of the 3 U.S. manufacturers of DTP vaccine stopped direct distribution last year, although one of these (Wyeth Laboratories) has continued to provide vaccine to Lederle Laboratories for distribution. The slowdown in distribution which resulted was met during the Fall of 1984 by drawing down on normal inventories of vaccine and by the sharing of vaccine by States with excess supply. However, the gradual shrinking of vaccine inventories during the Summer and Fall of 1984 and the production loss of vaccine scheduled for release in January-February 1985 created a situation in which supplies of DTP were limited and some areas

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could have been without DTP vaccine beginning January 1985. Therefore, on December 14, 1984 we recommended that the fourth and fifth doses be temporarily postponed to prevent an acute shortage. Since that time there have been some "spot" shortages which we have alleviated by working with Lederle and the various States to ensure that the small amount of vaccine which has become available has been allocated to providers in greatest need.

In the meantime, current production plans, if met, will permit us to meet current demands for vaccine during the Spring and Summer of 1985, and by the end of 1985 to replenish normal inventories and begin recalling children who missed their fourth and fifth doses.

The 1986 budget request continues the $8 million in the CDC Immunization grants added by Congress in 1985 for the first time to help partially defray the cost to the States of purchasing DPT vaccines whose price has increased significantly in the last three years. In addition, once current spot shortages of DTP vaccines are eased and a predictable supply stream is reestablished, we will begin purchasing DTP vaccines for the vaccine stockpile inventory. For 1986, $4 million are requested in the President's budget to continue developing the stockpile. We also recognize that liability concerns are a major problem in assuring vaccine supplies. This issue is currently being debated by the Congress, the public, and the Administration. Secretary Heckler has recently convened meetings of a Working Group of the Cabinet Council on Human Resources to discuss the issues of vaccine supply and liability.

VACCINE STOCKPILE

Question: You are requesting $4 million, the same amount available in FY 1985, to continue the development of a vaccine stockpile to include measles, mumps, rubella, polio, etc. If your goal is to maintain a 6 months stockpile of these vaccines, how much would it cost for the entire 6-months' stockpile?

Answer: Based on the amount of vaccine inventory purchased to date, approximately $40.1 million would be required to complete the six-month stockpile in FY 1986. Of this total, $32.3 million would be for the purchase of DTP vaccine.

Question: Why are you not requesting the full amount in your budget, but merely a $4 million down payment on the stockpile?

Answer: The stockpile effort was designed as a multi-year project primarily because of limited production capacity. Too rapid a build-up would have required manufacturers to suddenly increase their production and then gear down. Such an approach was judged to be uneconomical. Given that the majority of the stockpile that remains to be purchased is for DTP vaccines, it is particularly difficult to request that the manufacturers develop a six-month stockpile of DTP vaccines in one year when recent production and distribution problems have created spot shortages of the vaccine required to meet normal ongoing immunization needs.

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TUBERCULOSIS CONTROL REDUCTION

Question: In 1984 there were more than 21,000 cases of tuberculosis reported in the United States, a number of which were resistant to drugs. In view of this number and the danger inherent in the spread of drug-resistant tuberculosis, how can CDC justify the elimination of its tuberculosis grant program?

Answer: Although tuberculosis morbidity continues to occur in the United States, the decline in cases in 1982, 1983, and 1984 of about 7 to 9% a year, reestablished the downward trend that occurred before the arrival of Southeast Asian refugees. We are most concerned about the emergence of resistance to first line antituberculosis drugs, because the back-up medications are less effective, more toxic, and considerably more expensive. However, it is important to point out that even tuberculosis patients with drug resistant organisms can usually be successfully treated with the alternative, back up drugs.

When the Tuberculosis Cooperative Agreements are discontinued, health departments will have the option of continuing to support tuberculosis grant activities from other sources including State funds, local funds, or from the Preventive Health and Health Services Block Grants. The results of the Tuberculosis Cooperative Agreement programs funded in Fiscal Year 1982-1985 will enable State and local health departments to evaluate the priority of continuing tuberculosis programs along with the other competing program priorities. We believe that most high incidence areas will recognize the value of continuing the outreach program, as opposed to the options of (1) allowing non-compliant patients to continue to transmit infection in the community or (2) long-term hospitalization of non-compliant patients. The latter option would consume a large amount of State and local resources.

In addition to the federal funds available in the block grants, refugee funds are provided for overseas screening, inspection at points of entry, and State and local health assessment and referral services, including tuberculosis. These funds amounted to $6,049,000 in FY 1983, $8,450,000 in FY 1984, $8,090,000 in FY 1985, and the request for FY 1986 is $9,032,000. Approximately $2,700,000 of the funds for FY 1984, FY 1985, and FY 1986 will be used specifically for refugee tuberculosis preventive treatment services.

Question: What is the incidence of reported cases of TB in children? Is this incidence on the rise?

Answer: The 1983 case rate for tuberculosis in children under age 15 was 2.6 per 100,000. We do not believe that the incidence of tuberculosis in children in the United States is on the rise although we are concerned that the incidence in children stabilized from 1976 (1,775 cases) to 1981 (1,702 cases). In 1982, there were 1,349 cases reported in children, a decline of 20 percent from 1981. There was a slight increase in 1983 when 1,360 cases were reported in children under 15 years of age. Of the reported cases in children in 1983, 53 percent occurred in nonwhites (38 percent in blacks; 12 percent in Asians/Pacific

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Islanders; 3 percent American Indians/Alaskan Natives). In addition, 23 percent of cases in children occurred in Hispanics, almost all of whom are identified as white. Thus, about 76 percent of the total cases in children occurred in nonwhites and Hispanics. This year CDC and State/local health departments are completing a five year effort to implement a more comprehensive national tuberculosis reporting system. We plan to use the data available from this new system to conduct a more through analysis of the trends and causes of tuberculosis in children in the United States.

ELIMINATION OF DIABETES CONTROL PROGRAMS

Question: In your budget justification, you point out that diabetes costs more than 300,000 lives, 25 million hospital days, and $10 billion per year. Since 1977 CDC has provided funds for State diabetes control programs that your own justification notes are highly cost effective owing to reduced hospitalizations. Yet for the first time the budget proposes to eliminate them. Did CDC propose, in its original budget request to the Department, that funding for these programs be eliminated?

Answer: The elimination of the diabetes State demonstration projects was not proposed in CDC's initial request to the Department. However, during negotiations on overall spending plans for FY 1986, the Department agreed not to include funds for these projects in the budget request, since the initial purpose of these demonstrations had been accomplished.

Question: What indications do you have from the 20 States now participating that they are able to continue these programs without federal funds?

Answer: Over the past 5-8 years, 20 States have been federally funded to carry out diabetes demonstration projects. The goal of these programs has been to reduce complications of diabetes by improving the health care delivery system. A secondary goal of the program has been to achieve self-sufficiency. Many of these projects have been shown to be cost-effective and have developed comprehensive State plans for diabetes control and/or have ongoing community based projects. Programs which have benefited financially from their successes are encouraged to seek funding from State funds, block grant funds, private sector, or third party payment sources. In FY 1984, four to five States have made in-kind contributions of approximately $3.5 million while 15 other States have contributed a total of $1 million. In several States, third-party payers now cover the cost of certain services such as patient education. This number is expected to increase. In addition, other non-project States, such as Texas, Maryland, Iowa, and North Dakota, have either started their own diabetes control programs or secured third-party reimbursement for patient education without Federal financial support.

CDC will continue to provide technical assistance, develop consensus, and actively disseminate information on effective control and evaluation strategies. We will also continue to encourage States to establish linkages with organizations

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providing funds for service delivery in order to capitalize on existing resources, and will encourage use of block grant funding for diabetes control efforts.

MEASLES

Question: Over the past few months we have been hearing about measles epidemics on several college campuses throughout the United States. Why does it not seem possible to eliminate measles in this country, given the availability of a safe and effective vaccine?

Answer: While measles elimination has not been achieved, substantial progress has been made to date. Prior to vaccine licensure, over 500,000 cases of measles were reported annually in the United States. Over 57,000 cases were reported in 1977, when the childhood immunization initiative was started, and more than 26,000 cases in 1978 when the measles elimination program began. The provisional total of 2,534 cases in 1984 represents a greater than 99% reduction from the prevaccine era. In 1984, almost 94% of the nation's counties reported no measles cases. Thus, measles has been eliminated from the majority of the country. While measles outbreaks in 1985 have received considerable attention, only 339 cases have been reported during the first 12 weeks, a 39% reduction from the 558 cases reported during the first 12 weeks of 1984.

The exact reasons for the failure to eliminate measles are unclear. In 1984, approximately 2/3 of the cases occurred in persons for whom immunization was either not recommended or were exempt from current school laws. Over 1/3 of the cases should have been immunized and were not. It is believed that if these preventable cases could be eliminated, measles transmission would cease. Most of these preventable cases (56%) were in schoolage children. The remainder of the preventable cases occurred in preschool and postschool populations. The latter group, particularly college students, according to preliminary, information, will account for a substantial number of cases in 1985.

The CDC, working with other Federal agencies, State and local health departments, private practitioners, and with groups such as the American College Health Association (ACHA), is trying to overcome the last barriers to measles elimination. All outbreaks have been investigated by State and local health department staff to determine why outbreaks have occurred and to take aggressive control measures. CDC staff have assisted in the investigation of four of the larger outbreaks in 1985. Working with the ACHA since 1983, CDC has advocated requiring measles immunization for matriculation at colleges and universities. The ACHA has proclaimed a goal to implement that policy by September 1985. Greater efforts have been directed towards insuring preschool children are vaccinated at the recommended age of 15 months to ensure immunity well before school entry. States are encouraged to require measles immunity of all school students and to validate reports of immunization levels from schools.

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Question: Has there been any dramatic increase in the cost of measles vaccine, comparable to what has occurred with respect to the DTP vaccine?

Answer: There are primarily three vaccines used in college measles immunization efforts, measles vaccine, M/R vaccine (combined measles/rubella), and MMR vaccine (combined measles, mumps, rubella). There has been an overall increase of 2700% increase in the cost of DTP since 1982, compared to increases of 66% for measles, 70% for MMR, and 72% for M/R over the same period of time.

However, the actual dollar increase for the products containing measles antigen are not very different from DTP as indicated in the following table:

Increase In Cost of DTP, Measles, M/R and MMR Vaccine 1982-1985

Antigen	1982 Cost/Dose	1985 Cost/Dose	Difference	% Change
DTP	$0.11	$2.80	+$2.69	+2,700
Measles	1.70	2.82	+1.12	+66
M/R	2.43	4.17	+1.74	+72
MMR	4.02	6.85	+2.83	+70

STD'S -- HERPES

Question: Last year, in response to a question on the incidence of herpes, you informed the subcommittee that herpes simplex virus (HSV) infection is not a reportable disease in the majority of States, and that therefore morbidity trends were not available. Has CDC taken any action to encourage States to collect data on the incidence of herpes?

Answer: In 1984, CDC implemented a surveillance system for collecting and monitoring reported cases of genital herpes for males and females by each State. As States implement their reporting laws and regulations (expected to be completed by 1990) and achieve uniform definitions for cases of genital herpes, this surveillance system should provide useful data for planning control programs.

A year earlier, CDC had contracted for a surveillance system for neonatal herpes. Data from the system are currently being analyzed to identify preventable factors in this uncommon, though tragic, condition. Further defining and evaluating cost-effective genital herpes control strategies will benefit from enhanced surveillance activities.

Question: What are the current estimates as to the annual numbers of new reported cases and the number of Americans afflicted with the disease?

Answer: Between 200,000-500,000 new cases of genital herpes are estimated to occur each year. Prevalence estimates are as high as 20 million cases.

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Question: Is the availability of oral acyclovir, by reducing the frequency of recurrences of active infection in some patients, expected significantly to reduce the incidence of herpes in the United States?

Answer: Acyclovir will likely reduce the incidence of genital herpes; its potential for reducing disease transmission is unknown. Recent research findings highlight the increasing significance of the asymptomatic carrier and suggest that the impact of acyclovir may not be as great as originally anticipated.

USER FEES

Question: The CDC budget request provides for CDC to save $466,000 resulting from GAO-recommended user fees. Last year when CDC proposed to impose user fees, the Appropriations Committees denied the request indicating that this would be a threat to the public health since charging for services would discourage States from requesting CDC's help with reference diagnostic services. How does this year's user fee proposal differ from last year's proposal?

Answer: Last year, CDC proposed that $2 million in user fees be collected for reference diagnostic laboratory services provided to State and local health departments. The current proposal differs from the earlier proposal. This year, an estimated $466,000 in user fees are proposed for laboratory proficiency testing of commercial clinical laboratories and for providing reference reagents to private diagnostic product manufacturers. These services provide a clear benefit to the private manufacturers and commercial laboratories. This proposal will not have an adverse effect on public health, and CDC fully supports it.

PREVENTIVE HEALTH AND HEALTH SERVICES BLOCK GRANT

Question: Since 1982 the States have been receiving funding for various health and prevention programs under the Preventive Health and Health Services Block Grant. But we have had little information on the use of these funds by the States. Recently enacted legislation imposes new reporting requirements on HHS and the States. What action have you taken to develop model criteria and forms for the collection of data on services provided under the Block Grant?

Answer: As provided by the Legislation, we are directing requests for assistance to the involved health associations such as the Association of State and Territorial Health Officials, American Public Health Association, National Association of County Health Officials, and the United States conference of Local Health Officers. The agenda calls for representatives of these organizations to form a consensus group to provide consultation to the Department in the development of model criteria and forms, so that information can be collected as to the services provided under the Preventive Health and Health Services Block Grant.

Question: How do you plan to require the States to include in their annual reports a summary of services they provide and the population serviced?

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Answer: Each State and Indian Tribe receiving funds under the Preventive Health and Health Services Block Grant was notified by letter in October of 1984, when they received their initial FY85 award, of the Legislative requirements to include in their annual report the services being provided and the population serviced. The annual reports are due for FY 1985 in the Spring of 1986.

RAPE PREVENTION

Question: Legislative authority in the Preventive Health and Health Services Block Grant provides for services to rape victims and for rape prevention programs. What types of programs are being supported with these funds and how much is being spent?

Answer: The funds provided under the block grant are used primarily to support 24-hour crisis intervention hotlines, psychological counseling, victim assistance, and advocacy through all phases of medical care, legal investigation, consultation, and education for professional and the general public.

Three million dollars was provided during fiscal year 1984 as the minimum amount that the States must spend for rape prevention. The amount was increased in FY 1985 to $3.5 million. The States are allowed to spend more of the block grant allocation if they wish.

Question: How effective are these programs in preventing the occurrence of rapes in our society?

Answer: Because there has been no federally mandated reporting system under the block grant that requires the States to provide uniform information regarding program accomplishments, we have no means of measuring the effectiveness of this program.

FLUORIDATION/BLOCK GRANT

Question: Has there been any measurable change in the Nation's dental health resulting from the inclusion of the fluoridation grant program in the prevention block grant?

Answer: There is no evidence to indicate that the oral health of the public has been altered by the switch from categorical fluoridation grants to block grants in 1982. Since fluoride's effect on an individual and community basis requires several years to be manifest (i.e., children born in fluoridated communities today would initially show some benefits in the primary teeth in 3 to 4 years, benefit in permanent teeth in 6 years and beyond), it would not be possible to measure dental impacts today of decisions made to fluoridate or stop fluoridating in 1982.

Question: Are States and communities more or less likely to use block grant funds for fluoridation projects, absent a categorical program for this purpose?

Answer: It is not possible for us to speculate on what States and communities are likely to use their block grant funds

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for, in meeting their own priorities for preventive health services. However, two recent reports by the General Accounting Office (GAO/HRD-84-41, and GAO/HRD-85-33) concluded that under the block grant, the amount of expenditures for fluoridation programs had been maintained or increased in most of the 13 States studied by GAO.

OCCUPATIONAL SAFETY AND HEALTH TRAINING

Question: The fifteen University-based Educational Resource Centers (ERCs) which train occupational safety and health professions, have been federally funded for eight years. The CDC FY 1986 budget would eliminate ERC funding. Your own justification notes that in FY 1984, requests for health hazard evaluation and technical assistance increased by 20 percent over the previous year. In light of such increasing requests, how adequate is the supply of trained occupational safety and health professionals?

Answer: We do not have current comprehensive national supply and demand data on occupational safety and health professionals. We do keep track of the annual graduate levels from the ERC program. The most recent data are as follows:

Category	Number of Recent Graduates
Physicians	63
Nurses	42
Hygienists	257
Safety Professional	51

Question: Is there a danger that such training will cease without any Federal support?

Answer: The Educational Resource Centers (ERCs) were begun in 1976 to provide Federal support to start new programs in occupational safety and health and accelerate existing ones at universities across the country. Nine of the 15 university-based ERCs have had this Federal developmental support for eight years and have demonstrated the success of the program. The limited Federal grants ($400,000 - $600,000 annually) allowed programs to expand to meet increased student, employer, and public health interest in the occupational health field. We believe that continuing support for the ERCs should come from the non-Federal sources who benefit directly from the employment of occupational safety and health professionals having received academic or continuing education training from the ERCs.

While we cannot speculate on the fate of individual programs, we believe that the demonstrated abilities of the ERC program will encourage increased support from other non-Federal sources. It is estimated that the ERCs currently receive approximately 25% of their funding from sources other than the

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Federal training grant (i.e., States and private organizations). NIOSH is currently working with professional organizations seeking opportunities for private sector sources to provide funding for training efforts.

NIOSH - VDT STUDY

Question: We understand that NIOSH has abandoned its study of the possible effects of exposure to video display terminals on pregnant workers. Why was this study abandoned?

Answer: We have not abandoned the study. The study is proceeding according to schedule. At this point, we have identified a study population and developed a study protocol. The study, as proposed, will be an interview study of the reproductive function in a population of 2,000 married, non-management females, age 18 - 44 years, who use VDTs. This population will be compared to a similar group, of the same size, of workers not using VDTs. The objective of the study is to measure the association between occupational exposure to VDTs and adverse pregnancy outcomes, particularly spontaneous abortions.

We are in the process of obtaining clearances from our Human Subjects Review Board and the Office of Management and Budget and anticipate beginning our data collection in early Fall.

Question: What data does CDC have on the health problems related to VDT use?

Answer: There is some evidence that VDTs use can increase both physical and emotional stress on workers. Results from our surveys indicate that VDT operators report frequent visual and musculoskeletal strains and discomfort. The visual complaints are most frequently eye fatigue, eye irritation, and blurred vision. The musculoskeletal complaints are pain, or stiffness, in the neck, shoulders, back, arms, wrists, and hands. Questionnaire data indicate higher levels of psychological stress in VDT operators than in workers engaged in similar tasks, but not using VDTs. This may result from the VDT operator's perception of greater work pressures; loss of autonomy; involvement in fractionated, simplistic tasks; and their concerns about job security. There are numerous possible explanations given the widely varying work situations.

We do not find VDTs to be a source of dangerous radiation. There is no occupational exposure standard specifically for VDTs. However, all measurements of radiation emissions from VDTs are far below the present national occupational exposure guidelines and standards for radiation. The ultraviolet, visible, and infrared emissions are less than 1/100 of the allowable level in the applicable standard; the RF radiation and x-ray levels are less than 1/10 of the allowable limits.

Although no national standard has been established for extremely low frequency (ELF) radiation, measured levels from VDTs have been found to be less than those emitted by hair dryers, irons, and other typical household appliances. All forms of radiation measured were at levels well below those documented in

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the scientific literature as necessary for causing adverse biological effects.

Although we do not see any physiologic mechanism whereby VDTs could impair reproductive function, as yet we do not have sufficient information to rule out an effect of VDTs on reproduction. The study we are now conducting is designed to definitively answer the question.

Question: Just how serious are video display terminals to public health and in particular, to pregnant women?

Answer: As a whole, the findings to date suggest that visual and musculoskeletal problems are the most frequent complaints of VDT operators. These problems seem amenable to control by making ergonomic improvements which deal with workstation design, illumination requirements, work regimens and vision testing. The stress issues are more complex and are probably influenced by numerous factors in the workplace and not just the use of VDTs. Whether long-term VDT use causes significant visual dysfunction or degeneration remains unknown and requires further investigation. Based on extensive radiation measurements and reported health data, NIOSH has tentatively concluded that VDTs do not present a radiation hazard to the VDT operator or to the developing fetus, but further information is needed. No scientific evidence exists that the reported clusters of miscarriages and birth defects are associated with radiation exposure from VDTs. However, because alleged clusters of adverse reproductive health effects continue to be reported, we have initiated our current research to determine possible effects on adverse pregnancy outcomes.

CENTERS FOR HEALTH PROMOTION AND DISEASE PREVENTION

Question: On October 30, 1984, the President signed into law P.L. 98-551, which provided for the establishment of a network of centers for research and demonstration on health promotion and disease prevention. The Secretary delegated the responsibility for implementing the law to CDC; and on February 11 of this year the Director of CDC redelegated it to CDC's Center for Professional Development and Training. What action has CPDT taken to implement the new law?

Answer: No funds are requested for FY 1986 to implement this new program. Because of the overriding need for Federal fiscal constraint, other ongoing health programs are proposed to be frozen at 1985 levels or cut back. It is therefore difficult to justify starting new programs at this time. However, it is important to note that CDC currently spends about $1 million a year on cooperative agreements and contracts for research and demonstration on health promotion and disease prevention.

Question: If $3 million were provided for the program in the current FY 1985 supplemental appropriation, when would the first three centers become operational?

Answer: The necessary actions would be taken to make awards by September 30, 1985 if funds were appropriated for this program in the current fiscal year. They would be fully operational within 90-120 days after awards are made.

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STD'S -- RESEARCH EXPENDITURES

Question: How much does CDC plan to obligate, during FY 1986, for research with respect to gonorrhea?

Answer: CDC plans to obligate $1,392,000 during FY 1986 for research on gonorrhea.

Question: How much does CDC plan to obligate, during FY 1986, for research with respect to syphilis?

Answer: CDC plans to obligate $541,000 during FY 1986 for research on syphilis.

Question: How much does CDC plan to obligate, during FY 1986, for research with respect to pelvic inflammatory disease?

Answer: Pelvic inflammatory disease is the most serious sequela of gonorrhea and chlamydia and is the primary raison d'etre for investing in their prevention and control. Conservatively, at least 75 percent of the planned FY 1986 obligated research funds for gonorrhea and chlamydia could be labeled as pelvic inflammatory disease research.

Question: How much does CDC plan to obligate, during FY 1986, for research with respect to chlamydia?

Answer: CDC plans to obligate $1,582,000 during FY 1986 for research on chlamydia.

Question: How much does CDC plan to obligate, during FY 1986, for research with respect to herpes?

Answer: CDC plans to obligate $335,000 during FY 1986 for research on herpes.

Question: How much does CDC plan to obligate, during FY 1986, for research with respect to other sexually transmitted diseases?

Answer: CDC plans to obligate $659,000 during FY 1986 for research on other sexually transmitted diseases.

EMERGENCY MEDICAL SERVICES FOR CHILDREN

Question: The Preventive Health Amendments of 1984 (P.L. 98-555) included a new authority under the Preventive Health and Health Services Block Grant for demonstration grants to not more than four States for projects for the expansion and improvement of emergency medical services for children. What plans does CDC have for implementing this?

Answer: Funds to implement this new grant program were not requested in FY 1986. Because of the overriding need for Federal fiscal constraint, other ongoing health programs are proposed to be frozen at 1985 levels a cut back. It is therefore difficult to justify starting new programs at this time. Moreover, health block grant funds are available for such activities.

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INFECTIOUS DISEASES

Question: The Center for Infectious Diseases Hospital Infections Program provides data regarding hospital-acquired infections that are resistant to antibiotic drugs. In view of the increasing concern about the health threat posed by antibiotic-resistant bacteria, does CID plan to initiate a similar surveillance program for resistant infections acquired in the community.

Answer: CDC currently conducts surveillance programs which monitor the frequency of antimicrobial resistance of selected bacteria that cause community-acquired infections. These programs include: continuing meningitis surveillance; invasive pneumococcal disease surveillance; and a one-year national study of Salmonella infections, to monitor changes in antimicrobial resistance. During Fiscal Year 1986, CDC also will conduct a one-year national study of antimicrobial resistance of Shigella.

SUPERFUND

Question: The Superfund legislation calls for a number of health functions to be performed under the lead of the Environmental Protection Agency. These include support of toxic dump site inspections, research into the toxicological effects of human exposures to chemicals, the development of guidelines to protect the health and safety of dump site cleanup workers, and the establishment of inventories of research literature on toxic substances. What has the Agency for Toxic Substances and Disease Registry done, and what is it planning to do, to discharge these responsibilities?

Answer: The Agency for Toxic Substances and Disease Registry (ATSDR) is charged with protecting the public health from exposure to hazardous substances and is responsible for the planning and implementation of CERCLA health related activities. ATSDR fulfills much of its mandate through interagency agreements with other PHS agencies, and through cooperative agreements and contracts with States and other organizations, for specific activities. The following briefly summarizes the range of activities specifically assigned to ATSDR under the Superfund program:

- Determine the extent of danger to the public health from a release or threatened release of a hazardous substance. This mandate covers the range of health assessment and other support activities provided to the Environmental Protection Agency (EPA), States, and other Federal agencies at both emergency/immediate removal and remedial Superfund sites.

- Establish and maintain a registry of serious diseases and illnesses and/or registries of all persons exposed to toxic substances as a result of environmental exposure, whenever their inclusion in such registries would be scientifically appropriate or valuable for long-term followup or specific scientific studies.

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- o Establish and maintain a comprehensive and publicly accessible inventory of literature, research, and studies on the health effects of toxic substances.

- o In cases of public health emergencies caused, or believed to be caused, by exposure to toxic substances; assist, consult, and coordinate with private or public health care providers in the provision of medical care and testing of exposed individuals, including the collection and laboratory analysis of specimens as may be indicated by the specific exposure incident.

- o Conduct periodic surveys and screening programs to determine relationships between exposure to toxic substances and illness. This mandate includes in vivo and in vitro toxicological testing, human epidemiologic studies, and establishment of surveillance systems.

Accomplishments To Date

- o ATSDR has completed the implementation of four specific health provisions of Superfund. These include issuing a report of uniform data collection in November 1983; a report on registry development and maintenance in May 1984; a status report on the inventory of health effects of toxic substances maintained by the National Library of Medicine in November 1984; and a listing of areas closed or restricted because of toxic substance contamination in November 1984.

- o Assistance to EPA, the States, and other Federal agencies in providing health consultations at Superfund sites over the past three years has had significant growth. The numbers of consultations at remedial (or long term cleanup) sites grew from 87 in FY 1982, to 781 in FY 1983, to 827 in FY 1984. The numbers of consultations at emergency or immediate removal Superfund sites saw an even more dramatic increase from 12 in FY 1982, to 354 in FY 1983, and to 617 in FY 1984.

- o Nine major epidemiologic studies to assess the health effects of exposure to toxic substances at Superfund sites have been funded and are currently in progress. These include a study of dioxin exposure in Missouri, a study of mortality among workers exposed to dioxin using the National Institute for Occupational Safety and Health (NIOSH) registry; two lead exposure studies, one in Kellogg, Idaho and the other in East Helena, Montana; a study of multiple pesticide exposure around the North Hollywood Dump in Memphis, Tennessee; a study of arsenic exposure in Tacoma, Washington; and a PCB exposure study in New Bedford, Massachusetts.

- o Two studies, one in Georgia and one in Tennessee, have been initiated to investigate the relationship between low birth weight/developmental disabilities and exposure to hazardous substances at Superfund sites.

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- In the past two years, the National Library of Medicine (NLM) created 973 new or updated information records on hazardous substances found at Superfund sites which are publicly accessible through the NLM Toxicology Data Bank.

- Eleven chemicals or classes of chemicals identified as priorities for testing of chemicals found at Superfund sites have been put in test by the National Toxicology Program (NTP). Testing for three substances have been completed.

- 617 Federal, State, and local officials were trained in "state of the art" safety and health practices for cleanup of hazardous waste sites by NIOSH during the past year.

Planned Accomplishments for FY 1986

- Health consultations at Superfund emergency/immediate removal and remedial sites will level off during FY 1985 and FY 1986 with only a slight increase projected. We project that approximately 1,300 health consultation will be performed at Superfund sites during FY 1985 and 1,400 during FY 1986.

- The number of pilot health studies is projected to increase from FY 1984's level of 7 pilot studies completed, to 20 in FY 1985 and 20 in FY 1986.

- Birth defects studies to determine the relationship, if any, between adverse reproductive outcomes and exposure to toxic substances at Superfund sites will increase from those currently underway in Georgia and Tennessee to an additional 5 States in FY 1985, and another 3 States in the following year for a total of 10 by the end of FY 1986.

- Laboratory techniques for measuring minute changes and abnormalities in kidney and liver functions will be developed by the end of FY 1985. During FY 1985, the methods and protocol for national reference range studies in selected congeners for use as analytical standards will be applied to dioxins, furans, and PCBs.

- During FY 1985 we will begin to develop a battery of diagnostic immunologic tests which will reflect changes in immunologic competency. During FY 1987, we will begin to develop a battery of lipids and lipoproteins which reflect changes in the cardiovascular system.

- Guidance manual for occupational safety and health practices at hazardous waste sites will be published during FY 1985.

- The initial training program on occupational safety and health related to hazardous waste site cleanup will be completed in FY 1985. An advanced course is scheduled to be developed in FY 1987.

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- All current research projects to test the efficacy of worker protection clothing and equipment in use at hazardous waste sites will be completed by FY 1986.

- A new, easily used, computer system for toxicology and other health effects information will become totally operational in FY 1985 on a 24-hour basis. It will then be available to all States, as well as other Federal agencies.

- An additional 400-700 new or updated health effects information records on hazardous substances will be created and entered into the Toxicology Data Bank.

- Toxicological tests on all 24 chemicals or classes of chemicals that have been nominated as Superfund priority substances will be underway or completed by the end of FY 1986. In addition, a study of toxicity of chemicals mixtures will be initiated.

IMMUNIZATIONS

Question: Under amendments made in 1984 by P.L. 98-555, CDC's immunization authority is no longer limited to children. What plans does CDC have to take advantage of this extension of its authority.

Answer: Several steps have already been taken which are a natural outgrowth of our traditional childhood focus. We have initiated a program to eliminate rubella and therefore congenital rubella syndrome from the United States. These efforts will concentrate on ensuring that the estimated 15-20 percent of women of childbearing age who are not protected against rubella are identified and appropriately immunized. We have urged State level programs supported with grant funds to examine and implement activities which will assure better immunized young adults in colleges and universities as well as activities designed to cause hospital and health department personnel to be immunized. We have convened a meeting comprised of many different individuals, organizations, and businesses which have important roles to play in achieving better adult immunization levels and subsequently distributed a summary of that meeting, including commitments, made by participants. We have developed a request for contract which is designed to identify methods which will cause adult target groups to seek immunization.

STD'S -- PUBLIC INFORMATION AND EDUCATION PROJECTS

Question: How will CDC implement the provision in P.L. 98-555 to increase from 5 to 10 percent the amount of appropriated funds that are used for research, demonstration, and public information and education projects?

Answer: CDC has already allocated more than 10 percent of STD grant appropriations on 318(b) projects. CDC is implementing this provision through recommendations made in the Guidelines for STD Education and the Program Announcement for STD Grant Application. Grantees will be required to structure their

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programs to be in accord with the 1990 Objectives. The following three objectives are relevant to this question:

1. By 1990, all junior and senior high school students will receive timely and accurate information about STD.

2. At least 95 percent of health care providers seeing suspected cases of STD should be capable of diagnosing and treating all currently recognized conditions.

3. The proportion of sexually active men and women protected by properly used condoms should increase to 25 percent of those at high risk of acquiring STD.

Implementation will be further encouraged through CDC consultation with project grantees. CDC will continue to fund research, demonstration, and public information and education projects of national interest.

Question: How many information and education projects will be funded in FY 1985? FY 1986?

Answer: CDC is funding three public education and information projects in FY 1985. These projects have been approved for funding in FY 1986. Also, six projects have been funded in FY 1985 for developing STD training for professionals through medical schools, which will also be funded in 1986. Additionally, all 64 STD project grantees expend part of their award on public information and education. We expect to fund the same number of projects in FY 1986.

Question: What will they be designed to do?

Answer: The education and information projects in FY 1985 and 1986 are designed to do the following:

- Maintain the VD National Hotline which provides information and referral services to over 65,000 callers each year.

- Demonstrate the effectiveness of a behaviorally based STD education curricula in a pilot project for 5,000 school children in grades 7-12.

- Develop computer assisted training modules which promote STD prevention behaviors for junior high and senior high school students.

- Develop audiovisual materials to disseminate information and to promote therapeutic compliance with STD treatments.

- Demonstrate and evaluate the effectiveness of patient counseling as a tool for promoting patient compliance with treatment and followup recommendations.

- Develop strategies to promote condom use among STD clinic patients and high-risk groups.

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- o Develop and implement STD curricula in six university medical schools.

- o Sixty-four project grantees expend money to fund public information and education projects. These activities include:

  - Clinic-based patient education to improve future disease prevention potential and/or improve future health-seeking behaviors on the part of infected patients.

  - Community education efforts directed toward selected high-risk groups, such as pregnant females or homosexuals.

  - Education efforts directed toward school-based populations, particularly in the implementation of effective STD curricula within the nation's school systems.

INFLUENZA AND RELATED RESPIRATORY AILMENTS

Question: Influenza and related respiratory ailments, particularly the common cold, cause significant economic loss from reduced worker productivity, and may be life threatening to the aged and other population groups. Is CDC supporting a research effort directed at these ailments?

Answer: CDC programs on respiratory viruses focus on acute respiratory diseases, mainly of young children and influenza, mainly of high-risk adults.

Question: If so, what was its magnitude in FY 1984? What will be its magnitude in FY 1985? What magnitude is proposed for FY 1986?

Answer: Acute respiratory diseases of children have a high indirect economic cost, for they cause parents to be absent from work to provide care for children who have the highest rates of overt infections with such viruses as Respiratory Syncytial Virus, Parainfluenza Virus and Adenoviruses. CDC programs include research to assist the development of appropriate vaccines, to develop newer forms of diagnostic reagents and procedures, and to monitor the epidemiology of these diseases. These programs will continue in FY 1985 and FY 1986.

CDC programs in influenza are primarily directed at control of the disease in high-risk adults through improving use of current vaccines and the antiviral agent amantadine. Field studies by CDC staff and collaborators are undertaken each year to increase knowledge of the performance of vaccines. Studies in nursing homes have been undertaken to identify factors which may increase vaccine use, and a professional education program for operators and staff of such facilities is now being prepared and will be field tested in 1985 and 1986 to attempt to raise vaccination rates in homes for the elderly. CDC will expand

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influenza control activity through immunization staff assigned to State health departments.

ADEQUACY OF JUSTIFICATION

Question: Your justification does not adequately reveal how amounts requested for FY 1985 will be allocated among the various CDC components so as to serve the various purposes of the budget request. Please provide the subcommittee, for the record, with a detailed crosswalk that will enable the subcommittee to understand where the responsibility will lie, within these components, for obligating the CDC appropriations for each of the major CDC functions.

Answer: The requested crosswalk follows:

Disease Control, Research, and Training
Centers for Disease Control
Crosswalk of Budget Activity to Organization
FY 1986 Estimate

	Amount
Preventive Health Block Grants:	
Grants	$89,000,000
Program Support:	
Center for Health Promotion and Education	197,500
Center for Prevention Services	200,000
Support Services	98,500
Total Preventive Health Block Grants	89,496,000
Venereal Diseases:	
Grants:	
Center for Prevention Services	45,054,900
Evaluation	455,100
Total Venereal diseases - Grants	45,510,000
Program Operations:	
Center for Infectious Diseases	1,320,600
Center for Prevention Services	6,039,000
Laboratory Program Office	250,000
Support Services	1,797,400
Total Venereal Diseases - Program Oper.	9,407,000
Immunization:	
Grants:	
Center for Prevention Services	41,976,000
Evaluation	424,000
Total Immunization - Grants	42,400,000
Program Operations:	
Center for Infectious Diseases	1,759,000
Center for Prevention Services	4,372,000
Laboratory Program Office	250,000
Office of Director Program	33,600
Support Services	1,526,400
Total Immunization - Program Operations	7,941,000
Vaccine Stockpile:	
Center for Prevention Services	4,000,000

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	Amount
Infectious Diseases:	
Center for Health Promotion and Education .	114,022
Center for Infectious Diseases	31,217,666
Center for Prevention Services	2,620,593
Center for Professional Development & Trng.	1,422,356
Laboratory Program Office	7,139,563
Regional Office Staff	1,806,000
Support Services	8,468,800
Total Infectious Diseases	52,789,000
Chronic and Environmental Disease Prevention:	
Center for Environmental Health	9,847,900
Center for Health Promotion and Education ...	3,754,000
Center for Infectious Diseases	676,300
Center for Prevention Services	2,608,000
Center for Professional Development & Training	1,202,000
Support Services	5,637,800
Total Chronic and Envir. Dis. Prev.	23,726,000
Occupational Safety & Health:	
National Institute for Occupational Safety and Health	54,446,000
Support Services	3,089,000
Evaluation	110,000
Total Occupational Safety and Health	57,645,000
Epidemic Services:	
Center for Environmental Health	1,034,000
Center for Health Promotion and Education ...	2,757,500
Center for Infectious Diseases	17,636,000
Center for Prevention Services	2,687,100
Center for Professional Development & Training	1,188,000
Epidemiology Program Office	9,858,000
International Health Program Office	2,051,000
National Institute for Occupational Safety and Health.....	785,000
Special Projects	2,000,000
Evaluation	200,000
Support Services	8,711,400
Total Epidemic Services	48,908,000
Buildings and Facilities	7,297,000
Program Management	2,973,000
Total, Request	392,092,000

Questions Submitted by Senator William Proxmire

DAY CARE CENTERS

Question: I'm a little puzzled over your response to the growing problem of contagion in day-care centers. Health officials warned last year at a special conference to address the situation that some potentially dangerous childhood diseases are spreading because of the unprecedented number of children in

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day-care centers. An estimated 12 million youngsters -- a million of whom are under the age of 2 -- now spend most or part of their days in such an environment. Not only are these centers responsible for at least 10% of all hepatitis A cases annually, according to an article in the Washington Post, but approximately 40% of bacterial meningitis -- a life-threatening infection of the nervous system -- now occur there. It seems to me that what we're seeing is what we used to see in crowded Army barracks years ago, yet your statement addresses only the incidences of diarrheal disease and CDC's plan to develop training materials for use by day care-center personnel. Why is this?

Answer: CDC is initiating a contract for a nationwide study of infectious diseases in day-care settings. This study will enable CDC to determine the relative risk of specific infectious diseases by children who attend day-care facilities compared to children cared for at home. The study will provide information about diseases developed by the children in day-care and members of their families, characteristics of the childrens' day-care centers and homes, and economic costs associated with day-care related illness. The study will include not only diarrheal illness, but respiratory illness, vaccine-preventable disease, trauma, and accidental poisoning. A specific study of the risk of Haemophilus influenzae type b meningitis in children attending day-care facilities has recently been conducted by CDC. In view of the study results, a greater consensus on preventive measures, including prophylactic antibiotic treatment of certain contacts of meningitis cases in day-care facilities is being developed by CDC in collaboration with State and territorial epidemiologists.

Question: Wouldn't it also make sense to make immunization mandatory for all children in day care?

Answer: It would make a great deal of sense to mandate immunization of children attending day-care, for not all states require such immunization. Even in those states requiring immunization, there are many unlicensed facilities which do not fall under the authority of the existing state regulations.

Question: Does CDC plan any follow up of the health risks involved in these centers?

Answer: The information developed in the CDC day-care studies will continue to be used for the development of specific intervention approaches to reduce unnecessary morbidity and mortality associated with child care outside the home. Future work will include development, evaluation, and dissemination of intervention packages addressing regulatory, medical, and educational aspects of the problem. There will be periodic followup studies to assess the risks associated with day-care attendance. CDC also plans to continue updating information in the scientific literature about infectious disease in day-care facilities and to modify its intervention packet as necessary.

AGENT ORANGE HEALTH STUDIES OF VIETNAM VETERANS

Question: Dr. Mason, I was interested to learn of the recent birth defects study involving Vietnam veterans. As you know, my office has been in touch with the Director of CDC's Agent

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Orange Project regarding the exclusion of female Vietnam veterans from the congressionally mandated health studies now under way. I know CDC plans a related study of these 8,000 women but I'm curious as to why they were left out of the design in the first place. Can you tell us why?

Answer: The current study being conducted by the Centers for Disease Control (CDC) does not include women for several reasons. Most importantly, the sampling procedures used to select subjects for the current study of male veterans would not have generated sufficient numbers of women veterans to allow any meaningful conclusions to be reached about them as a group. That is, if women had been eligible for these studies in proportion to their representation in Vietnam, too few women would have been included to assess their health status with any reliability.

Moreover, at the time the original protocols were developed, there appeared to be three formidable operational obstacles to inclusion of female veterans. First, because gender was not recorded on any comprehensive listing of Vietnam-Era Army veterans, identification of women who served in Vietnam was thought to be problematic. Second, there were uncertainties about the existence of an appropriate comparison group for female Vietnam veterans. And third, location of women 10 to 15 years after completion of military service was thought to be difficult, particularly since many of these women would have changed their names pursuant to marriage or divorce. As a result of several feasibility tests, CDC now believes that none of these potential operational obstacles would prevent the successful implementation of the study of the health of female Vietnam veterans. Solving the problem associated with the operational obstacles means that enough women veterans could be identified to make the study scientifically feasible.

Question: What's the status of this proposal? I understand the Agent Orange science panel rejected it because it needed more study design.

Answer: The Agent Orange Working Group's Science Panel reviewed the issue of a study of the health of female Vietnam veterans at their March 20, 1985 meeting and is scheduled to report soon to the full committee.

Question: How does it compare with the health studies involving male Vietnam veterans already in the pipeline?

Answer: The proposed study of female Vietnam veterans is similar to the Vietnam Experience Study being conducted in males. That is, the study of female veterans would compare the health of Vietnam veterans to comparable veterans who served elsewhere. Any of the exposures women veterans experienced in Vietnam (e.g. stress of caring for a high volume of combat casualties, parasitic diseases, etc.) might influence the health of Vietnam veterans compared to other female veterans.

Question: How much do you estimate will be needed to implement the study?

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Answer: There is no formal scientific protocol or budget proposal for the study of women veterans. At the direction of the Agent Orange Working Group, CDC prepared a draft protocol outline for an epidemiologic study of female veterans. Based on decisions on whether or not to proceed with the study of female veterans, CDC would develop a detailed protocol and budget.

OCCUPATIONAL INJURIES

Question: Dr. Mason, you say that the incidence of work-related injuries dropped from 9.2 per 100 fulltime workers in 1978 to 7.5 per 100 fulltime workers in 1983. Well, I'm delighted to learn that the trend is a downward one. But, the number of workers who suffer these accidents each year--an estimated 10 million--is much too high. What's more, three million of these men and women are severely injured. What occupations present the highest risk?

Answer: For injuries, based on data from the Bureau of Labor Statistics from 1981, the ten occupations with the highest injury ratios (number of injuries to number or workers employed), beginning with the highest, are:

1. Warehouse laborers
2. All other non classified laborers
3. Structural Metal Workers
4. Roofers and Slaters
5. Sheet metal workers
6. Construction laborers
7. Freight, material handlers
8. Millwrights
9. Truck drivers
10. Mechanics, not classified.

Question: Have you recommended any new standards to the Department of Labor to protect workers in these areas?

Answer: In the last two years NIOSH has published seven documents providing recommendations for reducing injuries among high-risk worker groups. These documents are:

1. Construction Safety Standards for Excavations (1983)

2. Guidelines for Controlling Hazardous Energy During Maintenance and Servicing (1983)

3. Occupational Safety in Grain Elevators and Feed Mills (1983)

4. Comprehensive Safety Recommendations for Land-Based Oil and Gas Well Drilling (1983)

5. Comprehensive Safety Recommendations for the Precast Concrete Products Industry (1984)

6. Preventing Electrocutions of Workers in Fast Food Restaurants (1984)

7. Preventing the Injury of Workers by Robots (1984)

In addition, we recently (September 1984) published one document which addressed both safety and health hazards in the

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manufacture of paint and allied coating products. Two similar documents, one related to safety and health hazards in foundries and one on safety hazards in the manufacture of fabricated structural metal products, are expected to be published later this year.

Question: The review of death certificates has found increasing use as a technique for surveillance of fatalities caused by occupational injury. I understand NIOSH and the National Center for Health Statistics (NCHS) have been working with State health departments to develop a standardized method of reporting occupational data on these certificates. Has this been implemented yet?

Answer: NIOSH, NCHS, and the National Cancer Institute are working together to improve State health department recording of occupational information on death certificates. In 1979, only 11 States routinely coded occupation from death certificates. Now 26 States and Puerto Rico, New York City, and Washington D.C. are using a U.S. Census-based standardized coding system for industry and occupation. Furthermore, 34 States and independent registration areas have sent staff to NIOSH to be trained in the use of this system. Once the system expands to at least 30 States, we will have a sufficient national cross section to use its data in conjunction with census counts for estimating national work-related death rates. Ultimately, we hope to have all 50 States participating.

Question: What about the 22 States which have never routinely included any occupational data on death certificates?

Answer: In 1979, only 11 States routinely coded occupation from death certificates. Now 26 States and Puerto Rico, New York City, and Washington, D.C. are using a U. S. census-based standardized coding system for industry and occupation. Furthermore, 34 States and independent registration areas have sent staff to NIOSH to be trained in the use of this system. Once the system expands to at least 30 States, we will have a sufficient national cross-section to use the data in conjunction with census counts for estimating national work-related death rates. Ultimately, we hope to have all 50 States participating.

Question: Will they participate in the new data gathering system? If not, why not?

Answer: The system of coding occupation on death certificates is a voluntary program for the States. We have no authority to require that this data be coded. However, over the last six years, the increased participation by States in this system is an encouraging sign that we will ultimately have the minimum of 30 States necessary for a sufficient national cross-section.

MEASLES

Question: Dr. Mason, your statement points out that only 2,534 cases of measles were reported nationally last year, and that's excellent. But, I just wonder how many of these cases occurred on college campuses. The numbers seem to be rising here for some reason. Two years ago, for example, 20% of all cases

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reported took place on campus. If the present trend continues, these students could account for a substantial proportion of future outbreaks no matter how small. Because susceptibility among this population may be as high as 15%, according to CDC's estimates, the potential for sustained outbreaks exists. Have you considered recommending that schools require proof of measles immunity as part of admission?

Answer: The number of cases of measles on college campuses has fluctuated over the past several years. In 1983, 19.8% of all cases reported occurred in college students, whereas in 1984 preliminary data indicate that only 3-5% of cases were campus associated. Two large outbreaks in early 1985 have occurred, and it appears likely that college associated cases will again account for a substantial number of the total cases for the year. Because of concern about the susceptibility of college students to both measles and rubella, in 1980 CDC recommended that colleges require proof of immunity to these diseases for matriculating students. CDC has subsequently worked closely with the American College Health Association (ACHA) to educate college administrators about this concern, and in 1983, the ACHA adopted similar recommendations to become effective by September, 1985. In addition CDC has published several professional articles concerning the problem of measles and rubella on campus, and have presented several papers on the topic at the annual meeting of the ACHA. In addition, articles have appeared in the MMWR alerting the public health profession to the current outbreaks, and urging State health departments to adopt admission requirements.

ORAL SNUFF

Question: While the number of adult smokers may be on the decline, as your statement points out, the use of smokeless tobacco is on the rise in spite of warnings from health officials regarding the risk of oral cancer. The National Cancer Institute, Surgeon General and World Health Organization have all come out against the use of tobacco in this way, calling it a dangerous practice that may increase a person's risk of cancers of the mouth, pharynx and esophagus. Spurred on by television commercials which imply that using tobacco in this manner is a safe alternative to smoking, an estimated 22 million Americans — many of them teenagers unfortunately — use oral snuff. Has CDC ever addressed this problem?

Answer: The rising use of smokeless tobacco, especially among teenagers, is a concern. These products are habituating. Changes that they produce in tissues of the oral cavity have been linked to oral cancers. Many such products have a high sugar content, and may contribute to an increased risk of tooth decay. In general, however, very little is known about the epidemiology of smokeless tobacco use among adolescents and young adults.

CDC is studying the data currently available on the use of smokeless tobacco in the United States. We are assessing the feasibility of developing a questionnaire to be piloted in CDC's Behavioral Risk Factor Surveillance System. The questionnaire will address the epidemiology of smokeless tobacco use among adults in the United States. It will also retrospectively investigate the initiation, use, and cessation habits of users, as

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well as, other risk behaviors (including cigarette smoking) associated with the use of smokeless tobacco.

We have also been in contact with selected State Dental Directors to identify programs that address this health problem.

ADMINISTRATION

Question: What changes, if any, have you made in CDC's organizational structure since coming onboard?

Answer: Dr. Foege did an outstanding job when he reorganized CDC several years ago. All that I have done is to refine the structure that was in place.

SEXUALLY TRANSMITTED DISEASE PROGRAM

Question: Under existing law, at least 10 percent of the funds appropriated each year under the sexually transmitted disease program can be used for information, education, demonstration and research projects. Based on the budget request, that amounts to $5.5 million--not a great deal of money when compared with the estimated 10 million cases which occur each year. Can you tell us how these funds were used last year, what they're currently supporting, and your plans next year?

Answer: Current Congressional language require 10% of the STD grant appropriation to be used for information, education, demonstration, and research projects. Based on the $45.5 million grant appropriations in FY 1985, $4.55 million must be used for the above projects. In actuality, CDC has allocated $5,609,982 under Section 318(b) in FY 1985.

Category	Number of Projects	Amount
Research	6	$ 747,968
Demonstration	7	787,545
Medical School Curricula	6	471,381
Community Education	3	370,170
STD Training Centers	10	1,732,918
Public/Professional Education through STD Grants	64	1,500,000
TOTAL		$5,609,982

We plan to continue supporting the above projects during FY 1986.

Question: Your predecessor estimated that there are approximately 600,000 to 700,000 new cases of herpes infection annually. How close are we to developing a vaccine that might be useful to immunize against this infection?

Answer: A recently published document from the Institute of Medicine, National Academy of Sciences, reported on the current prospects for immunizing against herpes simplex viruses 1 and 2. This report concluded that studies of the therapeutic efficacy of inactivated whole virus vaccines have been found to have little success over the years. However, subsequent efforts have focused

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on vaccines containing glycoprotein surface antigens. These have been shown to be effective in stimulating immunity, reducing disease, and preventing death in experimentally challenged mice. Such vaccines also induce antibody in humans. Studies are under way to measure the vaccine's ability to prevent infection in adults not previously infected with Herpes Simplex Virus, type 2, whose sexual partners suffer from recurrent genital herpes.

Advances in molecular biology have made possible the development of genetically engineered attenuated live virus vaccines against HSV. These vaccines are expected to produce longer lasting immunity than the subunit vaccines. Some researchers believe that objections to the use of live HSV vaccines will diminish as genetic engineering makes possible the removal of regions of the genome responsible for cell transformation. The National Academy of Sciences concluded that, with a 90 percent probability of success, we are 5 years away from licensure of an HSV vaccine.

AIDS

Question: Dr. Mason, the Office of Technology Assessment feels the government ought to be doing more in terms of educating the general public as well as high risk populations concerning AIDS. In spite of the discovery of the probable cause of AIDS, a recent OTA study concluded —— and rightly so —— that prevention through education is the primary source of restricting the disease. To what extent, does CDC interact with these high-risk groups —— if at all?

Answer: CDC has maintained extensive interaction with communities and populations most affected by AIDS. Representatives of those groups have acted as consultants and participants on CDC projects, education programs, courses, and seminars. We strongly encourage State and local health departments to identify and work with community based groups representing populations where AIDS is of particular concern. In turn, CDC provides technical support and assistance to the health education efforts of non-governmental AIDS related groups and organizations. CDC has provided funds to the U.S. Conference of Mayors, selected health departments, and the National Hemophilia Foundation to assist with community-based AIDS information and education programs, and facilitate interaction between health departments and community-based organizations. A contract-supported study is being conducted to assess AIDS health education programs and collaborative relationships in nine States/cities. In addition, CDC conducted 44 AIDS workshops in 30 locations in February 1985 to provide updated AIDS information to health departments and community organizations and encourage interaction and collaboration on health education programs at the local level.

Question: What about programs to educate the general public? OTA estimates that within the next two years AIDS will move outside the existing risk groups and into the general population. Do you agree with this assessment? If so, what's being done now?

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Answer: The general population is at risk for AIDS through infected blood or blood products or through sexual contact with infected persons. The safety of blood and blood products should be improved with the application of the HTLV-III antibody test to screen blood and plasma. However, as the number of infected persons increases, the chance for sexual transmission also increases. Programs are underway to reduce the acquisition and transmission of HTLV-III virus through health education of risk groups. CDC is responsive to the health education needs of the general public in several ways. We provide information to State and local health departments through bulletins, seminars, and MMWR for redistribution to their constituencies. The national toll free AIDS hotline is open to the general public for taped information (800/342-AIDS) or to respond to individual questions (800/447-AIDS). In addition, we provide information and interviews frequently to the printed and electronic media.

INTERNATIONAL HEALTH

Question: Tell us briefly what areas of international health will be addressed next year and how much you plan to spend in this regard.

Answer: CDC's international health activities are those that can more efficiently be carried out overseas, such as quarantine visa activities and screening of refugees, and research studies necessary for improved domestic prevention and control programs that must be conducted in other countries because: the disease originated in the country and CDC is developing prevention and control programs (AIDS research Zaire and hemorrhagic fever research in Sierra Leone); and the disease does not occur in this country in sufficient numbers for research (malaria and parasitic diseases). Other international health activities included are epidemic aid, assistance to WHO, US agreements to cooperate with other countries (China), and global EIS. These activities reduce the likelihood that the disease will reach the USA and will reduce the continuing requests for epidemiology assistance in the future. We estimate obligating approximately $1.5 million in Disease Control, Research, and Training funds in FY 1986.

Question: Do you collaborate with the World Health Organization?

Answer: Much of the international activities of CDC are carried out under WHO auspices or in close collaboration. Also, there are 30 WHO Collaborating Centers located at CDC.

QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

RESEARCH AND TRAINING

Question: In the last decade, adult immunizations have proven effective in preventing tetanus, diphtheria, measles, rubella, hepatitis B, influenza and pneumococcal pneumonia. Persons with uncompromised health have exhibited a 60 to 70 percent prevention rate of pneumococcal pneumonia. What types of strategies have been developed in terms of education and public awareness for groups at high risk?

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Answer: CDC has convened a meeting comprised of many different individuals, organizations, and business which have important roles to play in achieving better adult immunization levels and subsequently distributed a summary of what happened at that meeting, including commitments, made by participants. As a result of this meeting, a national intervention strategy for adult immunization will be developed and implemented. We have developed a contract which is designed to identify methods which will cause adult target groups to seek immunization.

Question: What percentage of our nation's population falls into this high risk category?

Answer: Information is provided by diseases as follows:

Tetanus - Diphtheria: Recommendations presently suggest that if a primary series was received during childhood, the adult population should receive a tetanus diphtheria (Td) booster every 10 years. Further, assuming that the childhood population received a Td booster on schedule i.e., the last booster while in the school system at about 14 - 16 years of age, then the adult population 25 years of age and older should receive the Td booster. This totals 144 million people which is 61% of the total population.

Measles: In the traditional sense of defining high risk populations, i.e., aged and/or chronic disease category, this has not been done for the population in need of measles vaccine. The "high risk" category for measles vaccine is defined as that adult population born after 1957 and who lacks evidence of measles immunity, including all students presently enrolled in college. Data from serosurveys indicate 5% to 15% of college-age students are susceptible to measles.

Rubella: In the traditional sense of defining high risk populations, i.e., aged and/or chronic disease category, this has not been done for the population in need of rubella vaccine.

The "high risk" category for rubella vaccine is defined as the adult population of childbearing age women that have not demonstrated any antibodies to rubella as well as the population enrolled in college. Data from serosurveys indicate 10% to 20% of adolescents and adults are susceptible to rubella. Hospital workers are also encouraged to ensure adequate rubella immunization.

Hepatitis B: The high risk population recommended to receive Hepatitis B vaccine is male homosexuals, medical workers, end stage renal patients, drug addicts, and certain other ethnic groups. This is estimated to be about 9 million people.

Influenza and pneumococcal vaccine: Approximately 50 million people fall into the category which should receive influenza vaccine each year. This high risk group is defined as the population 65 years of age and older and

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those under 65 years with certain chronic health conditions, such as chronic lung condition, chronic heart condition, diabetes, etc. This same 50 million people fall into the high risk group to receive pneumococcal pneumonia vaccine.

Question: According to your statement, 24 States were assisted by CDC in establishing surveillance systems for key health behaviors, such as smoking, obesity, uncontrolled hypertension, heavy drinking, lack of seat belt use and sedentary lifestyle. The purpose of these surveillance surveys was to identify these health problems and define their prevention priorities. What types of measures have these 24 States taken to correct these problems?

Answer: The ongoing behavioral risk factor surveillance systems in 24 States have just completed their first year in operation. The data generated along with earlier point-in-time surveys have allowed States to compare risk factor levels in their State with national and regional rates. As a result, these States can more accurately and appropriately set priorities for their health promotion/risk reduction programs. We are now assisting States to build their capacity to analyze and interpret this newly available data and to develop and implement quality, effective risk reduction programs.

Ohio, for example, has used the Behavioral Risk Factor Surveillance System data to set State priorities and to distribute discretionary health funds based on these priority health problems.

Another example is in the community of Augusta, Maine. Community members recognized that teenage drinking and driving in connection with high school graduation celebrations were contributing to a soaring number of deaths each year. With full community backing a program of alcohol-free events at graduation time has now spread to over 100 communities in Maine, and has produced dramatic reductions in teenaged lives lost during the critical graduation weeks.

Question: What types of national awareness campaigns/ efforts has CDC undertaken?

Answer: National recognition and exposure to exemplary programs are given through the Secretary's Community Health Promotion Awards. Programs that received this recognition in the past have been adapted and adopted by other States and communities in addressing major health problems or risk factors.

Our primary role, however, is to improve the capacity of States to support organized, community-based intervention or risk reduction programs. Last year we launched a State assistance program in this regard. An integral part of the program is the use of behavioral risk factor data to determine priorities, and later, as a means to measure program effectiveness. It also provides a unique mechanism for bringing Federal, State, and community resources together to address targeted health problems in an organized and efficient manner.

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ALCOHOL, DRUG ABUSE, AND MENTAL HEALTH ADMINISTRATION

STATEMENT OF DR. DONALD I. MACDONALD, ADMINISTRATOR

ACCOMPANIED BY:

SHERVERT H. FRAZIER, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

WILLIAM POLLIN, NATIONAL INSTITUTE ON DRUG ABUSE

ROBERT G. NIVEN, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

KENT L. AUGUSTSON, DIRECTOR, DIVISION OF FINANCIAL MANAGEMENT

WILLIAM BELDON, BRANCH CHIEF, OFFICE OF THE BUDGET, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator INOUYE [presiding]. I would now take up the Alcohol, Drug Abuse, and Mental Health Administration, and receive testimony on the fiscal year 1986 budget request.

Dr. Macdonald, I believe, will be testifying.

Dr. Macdonald, I believe that this is your first appearance before the subcommittee. On behalf of the subcommittee, I welcome you. We look forward to receiving your testimony, but before you do, will you please introduce your colleagues at the table, and we will insert your statement in the record.

[The statement follows:]

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STATEMENT OF DR. DONALD I. MACDONALD

I am pleased to appear before you as Administrator of the Alcohol, Drug Abuse, and Mental Health Administration, to discuss the President's Fiscal Year 1986 budget request for our agency.

In this, my first appearance before the Subcommittee, I wish to express the great pride I feel in the productive pace of modern research into these costly and pervasive public health problems.

We deal with mental disorders and addictive states whose health consequences for individuals and their families are immense, as are their related costs. It is conservatively estimated that mental disorders and addictions at any one time afflict 30 to 45 million Americans and cost $30 billion annually in direct health care services. Taking into account indirect costs to society, including lost productivity, social services, accidents, fires, and crime control, a 1984 analysis estimates that in 1980 these disorders cost the U.S. economy $190.7 billion.

It is also now evident that mental disorders contribute to such stress related disorders as hypertension and violent behavior. As much as 50% of the mortality from the 10 leading causes of death in the United States can be traced to lifestyle (e.g., smoking, drinking), issues which are of central concern to ADAMHA.

Mr. Chairman, as you know, our agency's primary role is knowledge development - that is, providing a stable source of support for basic and applied research into these disorders. Also important is the development of strong linkages between research and clinical practice. ADAMHA continues to serve as the national resource for the collection, analysis, and dissemination of emerging knowledge concerning ADM disorders. Our role as a catalyst for knowledge transfer forms a vital bridge between research and

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practice among the variety of health care providers who serve people afflicted with these disorders. Moreover, the agency provides national leadership for consideration of alcohol, drug abuse, and mental health concerns critical to public health. Some examples are our informational efforts to increase awareness of these disorders by primary care providers and consumers, educational initiatives to improve the lot of children in high risk family situations, such as children of alcoholics, and collaboration with public and private groups to address the tragedy of the homeless and of young adult chronic patients.

Further, since passage of the Omnibus Budget Reconciliation Act of 1981, ADAMHA has administered the Alcohol and Drug Abuse and Mental Health Services Block Grant, reviewing applications, administering funds, conducting compliance reviews, and reviewing audits.

The President's budget request is based upon continuing the same level of effort as was requested in 1985. For the investigator-initiated research grants, this will result in continued stabilization at 500 new and competing awards. Where the Congress appropriated additional funds for this mechanism in 1985, we are proposing that the monies be used to multi-year fund about 38 grants. We are proposing this not only to maintain the level of 500 but, even more importantly, to save considerable continuation costs in 1986 and 1987. Other grant programs will be similarly held at their current level and the indirect cost rate for individual institutions will be limited to the rate in effect in 1985. With regard to research training, the budget provides for the same number of trainees - 984 - as in 1985. Since stipend increases to competitive levels were provided in 1985, no further increases are seen as appropriate for 1986 given the current budget restrictions.

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Before addressing our requests for FY 1986 funding, I would like to highlight some of the exciting findings that have resulted from recent ADAMHA supported research.

In the neurosciences, two pioneering efforts are clarifying the physiology of individual neurons. This basic research has begun to identify the mechanisms in the post-synaptic cell that are involved in mental disorders. We have found that certain phosphoproteins and the calcium concentration in the cell are linked to memory formation and schizophrenic disorders. Other studies on neuromodulators have shown that estrogens can both prevent and reverse drug-induced dyskenesia in laboratory rats. This offers a potentially new and intriguing line of research to be applied to humans in the areas of senility, including Alzheimer's disease, and other mental disorders whose treatment can produce socially devastating dyskenesias as a side effect.

Last year, the National Institute of Mental Health reported on the most comprehensive survey of mental illness ever conducted in this country. For the first time, the prevalence of specific psychiatric disorders, such as schizophrenia, the depressions, and the substance abuse disorders can now be reliably estimated. A representative sample from three sites around the country found that in the course of 6 months 19% of the Nation's population suffered from a diagnosable psychiatric disorder. The completion of this important survey will encompass two additional communities, and a total of 20,000 individuals, in institutions and out in the community.

Research supported by the National Institute on Drug Abuse has discovered that cocaine can be more dangerous than heroin and other commonly abused drugs. It was found that monkeys were three times more likely to use the drug in such a way as to cause death, than

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monkeys given free access to heroin. The danger of cocaine was clearly demonstrated by recent evidence from the Drug Abuse Warning Network that has shown an alarming increase in the adverse health effects of cocaine use. Progress has been made in understanding how drugs like cocaine and heroin produce their effects in the brain. These drugs, and possibly nicotine, activate, at different sites, what appears to be a common "reinforcement" circuit.

As to alcoholism, recent research has found that there is a genetic predisposition in up to 40% of alcoholics and that there is a genetic variability in a variety of responses to alcohol, including central nervous system sensitivity, development of tolerance and dependence, and susceptibility to alcoholic cirrhosis and psychosis. One striking hypothesis being explored in the area of neurophysiology is that appropriate measurements might identify individuals at risk even before they take their first drink. An NIAAA-supported project discovered unusual electrical phenomena in the brains of people who have a family history of alcoholism.

Mr. Chairman, we propose to maintain the level of effort that has brought us to new thresholds in medical research related to the brain and its functioning, the relationship of behavior to physical illness, and the biological and psychological processes involved in human addiction to chemical substances.

For mental health research, the President's request is $190.2 million. NIMH in FY 1986 will continue to put strong emphasis on brain and behavior research. For example, the Institute plans to initiate support for neuroscience research centers to promote multidisciplinary work on the neural basis of behaviors relevant to psychiatric illness. Scientists are actively investigating the "cascade of intracellular events" that follows the stimulation of a receptor by a neurotransmitter and of the neuromodulators which seem

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to regulate entire sets of neurons. Exploration into the internal mechanisms of neurons is key to the understanding of schizophrenia and the action of drug treatments.

Encouraging results in schizophrenia research reported in the past year will be pursued further. It appears that the traditional theory that increased dopamine activity is a cause of schizophrenia needs to be re-examined and refined. The dopamine system may act as a buffering system for mental equilibrium and, as such, schizophrenics may not be able to decrease their dopamine activity to maintain equilibrium. It is hoped that research to be undertaken with neuroleptic drugs will reveal more about this "down-regulation" process and about the role the drugs used to treat schizophrenia play in that process.

We will also build upon the progress being made in exploring the treatment of depression and manic depressive illness. Researchers intend to follow up on preliminary findings which indicate the prophylactic effectiveness of imipramine over lithium in controlling recurrences of unipolar depression. This could lead to improved drug therapies for patients now being treated with lithium.

Mr. Chairman, as you are aware, the devastating effects of Alzheimer's disease in the elderly have summoned the concerted efforts of several research Institutes and scores of neuroscientists throughout the country. In 1986, we plan to intensify our efforts to identify the cause of Alzheimer's and to improve its diagnosis. We also plan to explore innovative treatments for Alzheimer's victims, and to focus greater attention to the stress placed on families in caring for them.

At the other end of the life spectrum are childhood and adolescent disorders, such as autism, childhood depression, and

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attention deficit problems. About 2 million youngsters require immediate care for these disorders, and another 8 million need help. Research on childhood mental disorders is progressing steadily. Recent findings show, for instance, that prolonged administration of haloperidol improves behaviors in autistic children, and that the drug imipramine is a safe and effective treatment for depressed youngsters 6 to 12 years old. In addition to pursuing current lines of inquiry, NIMH in FY 1986 will undertake a special initiative on high risk minority children and youth. This will include studies of the interactions and developmental processes in families under stress, for example, those with a history of child abuse, or in which single parents must raise children in poor environmental settings.

For drug abuse research, the budget request is for $68.6 million, an increase of $4.5 million over FY 1985. Over the last few years we have been encouraged to find that levels of drug use by the young have, in general, declined. We have evidence to believe that this is partially the result of our prevention and education efforts. Nonetheless, drug use by the young, and by other age groups as well, remains unacceptably high and we are especially concerned by the continuing decrease in the age of first use of illicit drugs.

In FY 1986, NIDA will intensify basic investigations of the effects of drugs on the central nervous system. We believe these studies, which include investigations of the function signficance of endogenous opiate and receptor subtypes, efforts to map circuits, and efforts to identify receptors and endogenous substances which may be involved in the abuse of non-opiate drugs, offer the best long-term hope for the development of effective drug abuse prevention and treatment methodologies. NIDA will also expand its

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research on cocaine and the development of more effective prevention programs.

For alcohol abuse research, the budget request is $52.6 million, an increase of $4.6 million over last year. In FY 1986, the National Institute on Alcohol Abuse and Alcoholism would emphasize research on biomedical and genetic factors in alcoholism, and on the links between alcohol-related problems and consequent medical disorders. Scientists are studying a number of physiological and biomedical factors that may indicate predisposition to alcoholism, including brain waves, enzymes involved in alcohol metabolism, and blood levels of alcohol metabolites. Studies will continue into the alcoholic family environment, and the factors that promote drinking among adolescents, with the goal of designing more effective prevention strategies. Significant research will attempt to elucidate the effects of alcohol on many digestive, brain, and other medical disorders. While there is no known cure for alcoholism, an important development has been the movement toward improving classification of alcohol-related disorders, which can improve the physician's ability to assess individual cases and prescribe the most appropriate treatment.

Mr. Chairman, vital research on prevention is a special emphasis in all three agency Institutes, as now reported annually to Congress. We are intent upon strengthening the scientific foundation for preventive interventions against these disorders.

Our requests for FY 1986 funding are intended to allow us to build on our scientific advances and to develop additional insights that will enable more effective treatment and prevention of these devastating disorders.

Thank you. I will be glad to answer questions you may have.

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BIOGRAPHY OF DR. DONALD I. MACDONALD

Professional Positions:

1962 - Present - General Pediatric Practice, 1510 Barry Street, Suite C, Clearwater, FL 33516. Phone (813) 446-1161.
1980 - Present - Clinical Associate Professor of Pediatrics, College of Medicine, University of South Florida, Tampa, FL.

Education:

1952 - B.A. Williams College, Williamstown, Massachusetts.
1958 - M.D. Temple University School of Medicine, Philadelphia, PA.
1958 - 1959 - Rotating Intern, Duval Medical Center, Jacksonville, Florida.
1959 - 1962 - Resident in Pediatrics, St. Christopher's Hospital for Children, Philadelphia, Pennsylvania. (Chief Resident, 1961-62).

Certified:

1963 - American Board of Pediatrics

Fellow:

1963 - Present - American Academy of Pediatrics

Professional Organizations:

1962 - Present - The Florida Chapter of the American Academy of Pediatrics and the Florida Pediatric Society (President 1982-84).
1962 - Present - American Medical Association
1962 - Present - Florida Medical Association
1962 - Present - Pinellas County Medical Society
1975 - Present - Suncoast Pediatric Conference (Chairman 1975-80)

Professional Activities:

1980 - Present - Drug Abuse Committee of the Florida Medical Association (Chairman 1983-present)
1981 - Present - Scientific Advisory Committee, American Council for Drug Education (formerly ACM), New York, NY (President 1981-present)
1980 - 1982 - Director of Clinical Research, Straight, Inc., (Adolescent Drug Treatment Program) St. Petersburg, Florida
1970 - 1980 - School Health Medical Advisory Committee of the Florida Medical Association (Chairman 1975-77)
1970 - 1980 - School Health Medical Advisory Committee of the Pinellas County Medical Society (Chairman 1970-80)
1979 - Program Committee - Annual Meeting, Florida Medical Association (Nutrition)
1975 - 1979 - Nutritional consultant and lecturer, Florida Citrus Commission
1974 - 1976 - Committee on School Nutrition, Florida Medical Association (Chairman 1974-76)
1978 - 1983 - Consultant to Family Protection Team (Child Abuse), Children's Medical Services, St. Petersburg, FL
1962 - Present - Numerous committees, Morton F. Plant Hospital, Clearwater, FL (Chairman, Department of Pediatrics 1965-66, 1970-71, 1975-76)

Advisory Committees:

National:

1981 - 1983 - Board of Directors, National Federation of Parents for Drug Free Youth, Silver Springs, MD
1976- Board of Governors, American Red Cross

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Community:

1975 - Present - Junior League of Clearwater, Clearwater, FL
1982 - Present - Time-out Homes (Child Abuse), Clearwater, FL
1980 - 1983 - St. Petersburg Junior College School of Nursing, St. Petersburg, FL
1976 - 1979 - Chairman, District VIII Advisory Committee, Health and Rehabilitative Services, State of Florida
1965 - 1978 - Childbirth and Parent Education League of Pinellas County, Clearwater, FL
1970 - 1976 - Library Board, Clearwater Public Library, Clearwater, FL
1965 - 1975 - LaLeche League of Clearwater, FL
1964 - 1967 - Board of Directors, Play Parc (Retarded children), Clearwater, FL

Lectures: On drugs, drinking, adolescence, and parenting to a variety of groups in 22 states.

Medical Schools: (5 examples)

1984 - Southwestern Medical School, Dallas, TX
1983 - University of Florida College of Medicine, Gainesville, FL (Visiting Professor)
1983 - Children's Hospital Medical Center, University of Cincinnati, Cincinnati, OH (Visiting Professor)
1982 - Children's Memorial Hospital, University of Nebraska, Omaha, NE
1982 - Creighton University School of Medicine, Omaha, NE

Medical Organizations: (5 examples)

1983 - Mississippi Academy of Family Practice, Biloxi, MS
1983 - Napa and Sonoma County Medical Societies, Napa, CA
1983 - Greenville County Medical Society, Greenville, SC
1983 - Tom Green Eight County Medical Society, San Angelo, TX
1982 - National Medical Association Annual Meeting, Atlanta, GA

Hospital Medical Conferences: (5 examples)

1983 - Los Alamos Medical Center, Los Alamos, NM
1983 - Madison County Hospital, Jackson, TN
1983 - All Childrens Hospital, St. Petersburg, FL
1982 - Swedish Memorial Hospital, Littleton, CO
1982 - Winter Park Memorial Hospital, Winter Park, FL

Drug and Alcohol Conferences: (5 examples)

1983 - Southeastern Conference on Alcohol and Drugs (SECAD), Atlanta, GA
1981, 1983, 1984 - Annual Training Institute on Addiction, Miami, FL (1981), Clearwater, FL (1983, 1984)
1980 - 1983 - PRIDE Conferences, Atlanta, GA and San Francisco, CA
1983 - National Federation of Parents for Drug Free Youth (NFP), Arlington, VA
1982 - First Annual Governor's Conference on Drug Awareness, Montgomery, AL

And - Hundreds of talks and/or workshops for TV stations, radio stations, schools, PTA's, Junior Leagues, medical auxilaries, parent groups, church groups, and other civic organizations.

Personal:

Home: 1606 Beach Trail, Indian Rocks Beach, FL 33535
Phone: (813) 596-2347
Birth: April 15, 1931; New York, New York
Family: Married to Roberta ("Bobbie") Woodman; Children Sally, Jane, Andrew and Ian
Church: Hope Presbyterian Church, Clearwater, FL (Elder)
Military Service - U.S. Army 1952-54 (Honorable Discharge)
Fraternities: Phi Sigma Kappa, Phi Beta Pi

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Civic Organizations: 1962-66 - Clearwater Jaycees, Clearwater, FL; 1970-76 - Clearwater Breakfast Sertoma, Clearwater, FL

Awards - 1983 - Outstanding Service Award, PAR Inc., Pinellas Park, FL
1982 - Honary Lieutenant Colonel Aide-de-Camp, State of Alabama
1981 - Outstanding Community Service, Clearwater Junior Women's Club, Clearwater, FL
1969 - Outstanding Professional Service Award - Upper Pinellas Association for Retarded Children, Clearwater, FL

Publications

1. Macdonald, D.I.: School lunch, its past, its problems, its promise. Journal of the Florida Medical Association, May, 1979.
2. Barness, Coble, Macdonald, Christakis, Editors: Nutrition and Medical Practice. AVI Publishing, Westport, CT, 1981.
3. Macdonald, D.I. and Newton, M.: The clinical syndrome of adolescent drug abuse. Advances in Pediatrics, Vol. 28 (1981).
4. Macdonald, D.I.: Urine Screen for cannabinoids, a Pediatric view in Urine Testing for Marijuana use, Implications for a Variety of Settings. American Council on Drug Education, New York, NY, p. 36, (1981).
5. Macdonald, D.I.: Health and educational effects of marijuana on youth. Hearing before Subcommittee on Alcoholism and Drug Abuse of the Committee on Labor and Human Resources, U.S. Senate, October 21, pp 75-80, 95-100 (1981).
6. Macdonald, D.I.: The relationship of moderate marijuana use and adolescent behavior. In Marijuana & Youth - Clinical Observations on Motivation & Learning. NIDA, U.S. Department of Health and Human Services, pp 45-60 (1982).
7. Macdonald, D.I.: Let's Not Legalize Marijuana: Letter to J. Clyde Ralph, Practical Pediatrics in Pediatric News, New York, March, 1983.
8. Cupoli, J.M., Macdonald, D.I., Pitisci, G.J.: Changing life styles: Their effects on children, families and pediatricians. The Journal of Pediatrics, Vol. 102:6, 963 (1983).
9. Cupoli, J.M., Macdonald, D.I.: Editors. Proceedings of the Seventh Annual Suncoast Pediatric Conference, Clearwater Beach, FL, June 20-23, 1982 in the Journal of Pediatrics, Vol. 102:6, pp 963-1012 (1983).
10. Macdonald, D.I.: Comments in Adolescent Substance Abuse. Fourteenth Ross Roundtable on Critical Approaches to Common Pediatric Problems. Litt, I.F. (ed). Ross Laboratories, Columbus, OH (1983).
11. Macdonald, D.I.: The effects of alcohol and marijuana on the developing fetus. Int. Correspondence Soc. of Ob/Gyn Letters Inc., Lakeland, FL, Vol 24:19 p 148, (1983).
12. Macdonald, D.I.: A boycott of Squibb. NY State Journal of Medicine Vol 83:11-12, p 1151 (1983).
13. Macdonald, D.I.: Drugs, drinking and adolescence. American Journal Diseases of Children, Vol 138:2, Chicago, IL (1984).
14. Macdonald, D.I.: Drugs, Drinking, and Adolescents. Year Book Medical Publisher, Chicago, IL (1984).
15. Macdonald, D.I.: Evaluation and Management of the Adolescent Drug Abuser. Accepted for publication, Postgraduate Medicine, Minneapolis, MN, (1984).

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INTRODUCTION OF ASSOCIATES

Dr. MACDONALD. Yes, Senator Inouye.

From this end, Dr. William Pollin, Director of the National Institute on Drug Abuse; Mr. Kent Augustson, ADAMHA financial management officer; Dr. Shervert Frazier, Director of the National Institute of Mental Health; Dr. Robert Niven, Director of the National Institute on Alcohol Abuse and Alcoholism; and Mr. William Beldon from the Department Budget Office.

Senator INOUYE. Thank you very much.

Before proceeding, I would like to introduce Mrs. Domenici, in case you have not met her. She is a major force behind the U.S. Senate on matters relating to mental health. If you are smart, you will get in touch with her. Her husband happens to be Senator Domenici.

Please proceed, sir.

Dr. MACDONALD. I must say that I had a marvelous time in Albuquerque this weekend. Your name was mentioned by many, many people, and I am delighted that you are here.

I am delighted to be here, Senator. This is my first time and it is a little nerve racking, but I am sure I will get through it.

I thought, before I started, that I would make a few comments about how I see ADAMHA fitting into the mission of the Public Health Service, and what some of my own personal priorities are.

ADAMHA MISSION

The main mission of the agency, as I see it, is consistent with the priorities of our budget, and 80 percent of our budget is for research. We have some exciting things going on, and there are some exciting things that we have done. Perhaps in the questions we will cover some of the progress that has been made to date.

The second mission is taking research findings and transferring them into vehicles for use by consumers, providers, and practitioners. I think that we can accomplish more knowledge transfer with less money if we use some mechanisms that I don't think we have used as well as we could in the past.

The third mission ties those two together, and that is acting as a focus for the development of national strategy to deal with alcohol, drug abuse, and mental health disorders. That is sort of a combination of the first two, taking what research findings we have, which are not always complete, and using them to address important national problems of which there are many in this field. For example, as you well know, 50 percent of the people who die in this country of the top 10 diseases have a strong stress component related to one of the ADAMHA disorders.

The fourth priority area, and this comes from my background as a pediatrician, is my concern for prevention. If I have a special interest group that I represent, it is children. I am concerned not only about those children who are involved with ADAMHA disorders themselves, but also those children who have parents with disorders. I am con-

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cerned about those young people whose parents are in methadone treatment. I am concerned about young people whose parents are homeless. I am concerned about young people whose parents are alcoholics. We will stress prevention in the time that I am in this office, and the many related opportunites in science and in service coordination.

In conclusion to my brief statement, let me say that I am absolutely delighted with the job and with the opportunity it presents. I am open to questions, as are all of us.

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ST. ELIZABETHS HOSPITAL

STATEMENT OF DR. SHERVERT H. FRAZIER, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

ACCOMPANIED BY:

WILLIAM G. PRESCOTT, SUPERINTENDENT, ST. ELIZABETHS HOSPITAL.
JAMES E. PITTMAN, EXECUTIVE OFFICER, NATIONAL INSTITUTE OF MENTAL HEALTH
PERCY E. GOODY, BUDGET OFFICER, NATIONAL INSTITUTE OF MENTAL HEALTH
WILLIAM BELDON, BRANCH CHIEF, OFFICE OF THE BUDGET, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator INOUYE. Before proceeding, may I call on Dr. Frazier who would like to present a statement on St. Elizabeth.

We will insert your prepared statement in the record and then you may proceed.

[The statement follows:]

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STATEMENT OF DR. SHERVERT H. FRAZIER

Thank you for the opportunity to present the budget request for Saint Elizabeths Hospital. This has been the subject of continuing discussion between the Congress, Executive Branch, and District of Columbia government for the past several years. On one hand, we have been faced with the seeming inconsistency of the Federal Government operating a Hospital which primarily serves the residents of the District of Columbia. On the other, the District has been understandably concerned about the added expense to District taxpayers of assuming responsibility for an institution of this size.

Last year, we worked together to resolve this issue and obtain passage of legislation which would fix, on a permanent basis, the respective governmental financial responsibilities toward the Hospital. On November 9, 1984, the President signed Public Law 98-621, The Saint Elizabeths Hospital and District of Columbia Mental Health Services Act. This Act accomplished the mandated resolution of Federal and District financial responsibility for the operation of Saint Elizabeths Hospital and takes the further step of accomplishing transition of full management of local public mental health services to the District government. I would like to briefly summarize the most important aspects of this major legislation:

- The Act transfers responsibility for providing mental health services currently provided by Saint Elizabeths Hospital to the District government on October 1, 1987. The appropriate property, programs and staff of the Hospital will be transferred to the District.
- It requires the development of a comprehensive mental health services delivery plan by the District government by FY 1987.
- It authorizes Congress to appropriate a total of $84.0 million between FY 1988 and FY 1991 as the Federal share of support for operation of the Hospital. It further authorizes Federal

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appropriations totalling $135.0 million between FY 1986 and FY 1991 to the District as a "special subsidy" for mental health services delivery in the District of Columbia.

- o It creates continuing Federal liability, beginning in FY 1987, for services rendered to the following three patient categories:
  - patients referred as a result of a criminal proceeding in a Federal Court for any purpose,
  - patients referred from Federal agencies or under Federal statutes, and
  - patients taken into custody on specified Federal property, or for harming or threatening harm to a Federal official.

These provisions recognize that certain patients will continue to be a Federal responsibility after transfer to the District government.

- o It provides for specific, detailed safeguards for current employees of the Hospital, including but not limited to the same basic rate of pay, elective participation in the Federal Civil Service retirement system for certain employees, and rights of first refusal of employment in the District's public mental health system, the D.C. Department of Human Services, the D.C. General Hospital, and the Federal Department of Health and Human Services.
- o Perhaps most importantly, the Act reflects the intent of Congress, and I might add of all the parties involved, that the District operate a high quality, integrated, community-based public mental health system which provides good services -- consistent with patient rights -- in accredited facilities, with special provision for services to the homeless mentally ill.

With passage of the transition legislation, the Hospital's focus is on both patient care and helping to plan for a comprehensive mental health services system.

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Patient Care Programs

Hospital staff and District government officials are committed to assuring that transition planning in no way interferes with the delivery of good quality patient services. Continued emphasis will be placed on discharge of those hospital inpatients who can be better served in alternative therapeutic settings, consistent with the Dixon v. Heckler Implementation Plan. In fact, our discussions with the District reflect added emphasis in this area, with planning initiatives directed not only at direct psychiatric services but also enhancement of available residential and therapeutic placement alternatives. It is expected that these efforts will result in a further decline in the Hospital's daily average inpatient census, from the current projection of 1,559 in FY 1985 to 1,438 in FY 1986. Consistent with its commitment to continue delivery of appropriate outpatient services, the Hospital expects that it will maintain its current outpatient census of approximately 2,800 patients.

The Hospital will also improve dramatically the quality of its inpatient environment during the next eighteen months as it opens approximately 1,000 replacement beds in buildings which have been renovated as part of the $66 million renovation program initiated in 1978. These buildings have superior residential qualities which comply fully with both life safety code and patient privacy needs required by the Joint Commission on the Accreditation of Hospitals.

In reference to accreditation, the Hospital underwent a full survey by JCAH in October, 1984. We have now been informed that the Hospital has received its second consecutive full three-year accreditation. As we reported last year, the Hospital's Area D Community Mental Health Center has also received a full three-year accreditation which extends to October 1986. The Hospital also continues to retain its Medicare and Medicaid certification.

We are particularly pleased with the results of our recent surveys because they find continued quality care despite the reduction-in-force

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conducted at the Hospital in December, 1983. This fact is directly attributable to the demonstrated dedication of the staff at the Hospital and continued management improvements which have been and are being implemented there. It also reflects the salutary effects of the District's FY 1985 commitment to assist in reducing the Hospital's inpatient population through outplacement and direct operation of the Hospital's residential alcohol and drug abuse treatment program. Through our joint efforts, one hundred and eighty-eight (188) patients have been placed in nursing homes, and forty-three (43) have been placed in specialized residential facilities since October, 1983. The District has been operating its own eighty-nine (89) bed alcohol and drug program since April, 1984.

Planning

The transition legislation mandates that the Mayor develop his comprehensive mental health services plan in "close consultation with officials of Saint Elizabeths Hospital". Hospital staff have shown a strong commitment to provide their unique expertise to support this planning process and, ultimately, the implementation of a service delivery system singularly suited to meet the treatment needs of the mentally disabled of the District of Columbia. The Mayor has already convened a senior planning committee whose membership includes the DHHS Deputy Assistant Secretary for Health Operations, the Executive Officer of the National Institute of Mental Health, and the Superintendent of Saint Elizabeths. A Mental Health Systems Reorganization Office has been created and two senior SEH clinicians have been assigned, full time, to its staff. Numerous work groups have been established and Hospital staff have volunteered to participate on each. A constructive sense of cooperation permeates this entire activity.

Consistent with the requirements of the Act, work is proceeding in order to complete a preliminary plan for submission to the Mayor in the

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spring, followed by a detailed draft in December. Despite the complexity of the task at hand and the short time table, we are confident that our efforts will result in both a timely and quality submission.

Planning is not only proceeding for a comprehensive system; it is also proceeding internally as it relates to the Hospital's current and future mission, with coordination among all of the planning efforts. The Hospital is reviewing a draft internal reorganization plan designed to achieve organizational efficiencies now. It is conducting a long-term automated data processing planning study. It is conducting management studies designed to assess and provide for implementation of more efficient services in the areas of construction trades, medical services, pharmacy, and laboratory. It is planning and will implement a more accurate and efficient cost accounting system. All of these activities are designed to accomplish better service delivery now as well as to make the Hospital better prepared to continue its historic contribution to District mental health care in the future.

In addition, the Act requires that full financial and physical plant audits of the Hospital be conducted this year. Both requirements are being met through contracts. Hospital management views these audits as additional vehicles through which improvements in the quality of its services can be achieved.

Budget Request

The total 1986 budget request for the Hospital is $128,895,000, representing a net increase of $2,152,000 over the 1985 level. The net increase reflects several offsetting factors. Included are operating fund increases totalling $9,679,000, and reductions for nonrecurring 1985 expenses totalling $3,499,000. Total increases are further offset by $4,028,000 due to the proposed 5 percent reduction in pay for all Federal employees. As I indicated earlier, the proposed budget permits

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continuation of all clinical programs at 1985 levels, and for execution of anticipated management initiatives.

The HHS budget request proposes a direct Federal appropriation of $42,488,000, representing a net decrease of $6,107,000 below the 1985 amount. The District government share is projected to be $62,781,000, including its portion of projected Medicaid reimbursements, representing a net increase of $7,822,000 above the 1985 amount. Other independent reimbursements are projected to be $23,626,000, excluding the District share of Medicaid.

Calculation of the District's share represents the fourth year of a ten year plan for increasing District financial responsibility for Hospital operations. This plan is consistent with the transfer legislation and continues in effect until the full financing provisions of the transfer legislation take effect in FY 1988. The District share in 1986 is partially supported by the $25,000,000 special subsidy authorized to be appropriated in the transition legislation.

Mr. Chairman, I will be pleased to answer any questions which you or members of the committee may have.

BIOGRAPHY OF DR. SHERVERT H. FRAZIER

Personal Information: born, Shreveport, Louisiana, June 21, 1921; married Gloria Barger; four children--Elise F.; D. Alan; Rosalie F.; Stephen P.

Education: Bachelor of Science, University of Illinois, Chicago, 1941; Doctor of Medicine, University of Illinois College of Medicine, 1943

Postgraduate Medical Education: Medical Internship, University of Illinois Research and Educational Hospital, 1943; Fellowship in Internal Medicine, Mayo Clinic, Rochester, MN, 1951-1952; Fellowship in Psychiatry, Mayo Clinic, 1952-1955; Master of Science in Neurologic Sciences, University of Minnesota, 1957

Medical Licensure and Board Certification:
Medical License: CA, IL, MA, MN, NJ, NY, TX
Board Certified in Psychiatry, American Board of Psychiatry and Medicine, 1956; in Psychoanalytic Medicine, Columbia University Psychoanalytic Clinic.

Honors: Mayo Foundation Distinguished Alumnus Award, 1983; Camelback Hospital Humanitarian Award, 1981; Alpha Omega Alpha Honor Medical Society; Master of Arts, Harvard University (Honorary), 1972

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Professional Experience:

1984 -	Director, National Institute of Mental Health, Alcohol, Drug Abuse, Mental Health Administration, DHHS
1972 - 1984	Psychiatrist in Chief, McLean Hospital, Belmont, MA; Professor of Psychiatry, Harvard Medical School, Boston, MA
1968 - 1972	Deputy Director, New York State Psychiatric Institute; Professor of Clinical Psychiatry, Columbia University College of P&S; Attending Psychiatrist, The Presbyterian Hospital of New York and St. Luke's Hospital, NYC
1962 - 1968	Director, Houston State Psychiatric Institute (1962-1965); Psychiatrist in Chief, Ben Taub General Hospital, Houston; Professor and Chairman, Department of Psychiatry, Baylor University College of Medicine; Commissioner of Mental Health and Mental Retardation, State of Texas (1965-1966); Executive Deans Committee, Baylor University College of Medicine (1966-67)
1958 - 1963	Joske Assistant Professor of Psychiatry, Columbia University College of P&S (1959-1962); Director, Inpatient Consultation Service in Psychiatry, Presbyterian Hospital (1961-1962); Chief Research Scientist in Internal Medicine, New York State Psychiatric Institute (1958-1961)
1955 - 1958	Staff Psychiatrist, Mayo Clinic; instructor in psychiatry, University of Minnesota
1948 - 1951	Administrator, Harrisburg Medical Foundation, Harrisburg, IL
1946 - 1951	Private Practice, Medicine, Harrisburg
1944 - 1946	Medical Officer, U.S. Navy

Memberships & Professional Activities (Selected): American Medical Assn, 1943 - ; American Psychiatric Assn, 1956 - (Secretary, 1983 -); American Society of Human Genetics, 1959 - 1978; New York Academy of Medicine, 1960 -; Veterans Administration, consulting positions, 1962 - 1984; American College of Psychiatrists, 1963 - (President, 1979-80); Association for Research in Nervous and Mental Disease, 1964 - (President, 1972-73); American Board of Psychiatry and Neurology, 1965 - 1982 (President, 1972-73); World Psychiatric Association, 1975 - 1984 (Vice President, 1977-84); American Association for the Study of Headache, 1979 -.

FUTURE OF ST. ELIZABETHS HOSPTIAL

Dr. FRAZIER. Senator, it is a pleasure to be here.

As you know, this last year, in November, the President signed the legislation for the St. Elizabeths Hospital and the District of Columbia Mental Health Services Act. This legislation came after a lot of years of uncertainty. It resolves the question of responsibility for the future for St. Elizabeths Hospital, its operations, and its financing.

This is done through a clearly defined set of action steps. On October 1, 1987, the District of Columbia becomes responsible for the services and the programs of St. Elizabeths Hospital. By October 1, 1986, the District must complete a final comprehensive mental health services delivery plan.

From 1988 through 1991 inclusive, the legislation authorizes the Congress to appropriate up to $84 million as the Federal share of support in the operation of the hospital.

The legislation further authorizes the District of Columbia to request up to $135 million between 1986 and 1991 as a special payment to its appropriation for mental health services delivery in this transitional period.

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Both Federal payments cease after 1991. However, the Federal Government will continue to provide for its beneficiaries by reimbursement to the hospital for their care. These beneficiaries include persons referred pursuant to Federal law or who are the responsibility of a Federal agency, White House cases, and individuals referred as a result of Federal court proceedings.

The legislation has also taken into consideration the needs and the safeguards for the employees of the hospital. That is important because we want the services to flourish and not to diminish. We want the services to be comprehensive, top level and excellent.

We are going forward with this, and I am happy to report that the Transition Committee is meeting about twice a month now, and it is on target. The District and everyone is extremely cooperative in this effort. I think that it is a very fine demonstration of good faith in the process.

Senator INOUYE. Thank you very much.

MULTIYEAR FUNDING

Dr. Macdonald, I would like to begin with a question relating to the multiyear funding for new and competing research grants.

Senator INOUYE. I understand that instead of funding 583 new grants, as Congress intended, you are planning to fund only 500 new grants, 38 of which will be funded on a multiyear basis.

I am certain you are aware that the GAO recently issued an opinion on the NIH multiyear funding issue which is equally relevant to your agency, and I quote:

> The executive branch plan to fund some 646 NIH research grants on a 3-year basis with fiscal year 1985 funds is unlawful, because in the absence of specific statutory authority such actions violate the United States Code.

Will you give this committee your assurance that you will not seek to fund any grants on a multiyear basis?

Dr. MACDONALD. Senator, obviously that decision will be made by the Secretary, and we will certainly follow the guidelines of the law. I can't comment on the legal merits of the GAO position; people with more legal knowledge than me will have to advise me on this issue. We intend to make no multiyear funding grants at this time, but the final decision depends on the outcome of this discussion and what legal advice we get.

ADDITIONAL COST OF GRANTS

Senator INOUYE. Assuming that you were to fund the 583 grants as mandated and intended by the Congress, how much more would you have to add to this budget?

Dr. MACDONALD. We estimate it would be $19.4 million for continuation costs. If we were to fund 583 again in 1986, we would require another $10.3 million. So it would cost something like $30 million in total for a level of 583 new and competing awards.

Another option would be to fund 583 new grants this year, and then keep the same level of funding as currently requested for 1986. If we

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were to do that and meet all continuation costs,, we would have to drop back to an estimated 354 new grants. That $30 million requirement would cut seriously into our 1986 plans.

PROPOSED STAFF REDUCTIONS

Senator INOUYE. The conference report of the 1985 appropriation bill mandated your agency to maintain 1,664 full-time equivalent positions. However, your budget justification states that only 1,527 FTE's will be supported in fiscal year 1985, a reduction of 137 from the level provided by Congress.

How do you justify this reduction in staff below the congressionally specified levels?

Dr. MACDONALD. I think there are a number of issues involved in your question, Senator Inouye. One is that although additional funding was provided to restore FTE's, we have used that money to absorb pay raise increases. The general reason for reducing FTE's is an attempt to streamline our direct operations accounts. The number that we accrued in 1984 was 1,628 FTE's, and our current use rate is not really quite that high because in preparing for 1985, we slimmed down some at the end of the year.

It is the result of budgetary streamlining, looking at our internal operations and seeing if we can operate more smoothly.

Senator INOUYE. Was this an OMB directive?

Dr. MACDONALD. It was part of the overall plan that came from the OMB.

Senator INOUYE. What will be the effect of this reduction on your programs in view of the fact that your budget was increased by almost $77 million over fiscal year 1984?

Dr. MACDONALD. We don't think that it will have a serious impact for several reasons. We have, as you see in the budget, tried to protect our intramural program. In terms of the slight FTE reduction, 30 positions is all it will take to get down to the budgeted level in 1985, and we are going to straightline that level into 1986.

There is an additional reduction of 23 FTE's that will be required if clinical training is not reintroduced into the budget, or if CSP is not restored in 1986. We are going to reduce direct operations positions.

Senator INOUYE. So you will have to RIF 39 persons?

Dr. MACDONALD. As far as RIF's are concerned, the method that the OMB and the Department have both proposed is that we reach lower FTE levels by a hiring freeze and resulting attrition. We estimate our attrition rate to be 6 percent per year. In 1985, we won't make our budgeted number of 1,527, but the Assistant Secretary for Health has given us 20 extra FTE's to cover the overage and we will have to examine where we are entering 1986. We think that we will still be higher than our budgeted level for the year.

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Senator INOUYE. NIMH has been supporting research into the mental health aspects of AIDS. How are these research findings being translated into services to prevent and treat the psychological programs of those individuals already afflicted with AIDS, as well as those at risk of contracting the disease?

Dr. MACDONALD. Dr. Frazier may want to comment on that.

We have straightlined our AIDS budget of $2.8 million from 1985 into 1986. Dr. Mason, who is now the Acting Assistant Secretary for Health, chairs a subcommittee on AIDS to which we send two representatives, one representing the National Institute on Drug Abuse, knowing that AIDS is particularly prevalent in that population, and another from the National Institute of Mental Health, Dr. Silver.

Dr. Silver's input is in dealing with those issues of AIDS which relate to mental health, such as the concern that people obviously have about the blood test, and what people are to do when they find out that they have a positive test.

We have launched an extensive educational effort, comprised of material for blood bank personnel, material for mental health professionals, and material for physicians whom AIDS victims will come to. That has been part of our overall effort.

Maybe Dr. Frazier would like to add something.

Dr. FRAZIER. The task force is working with CDC in Atlanta closely, and they are developing publications and handbooks for distribution at blood bank centers and to all interested parties.

In addition, we are conducting research in the psychosocial, psychiatric, and the behavioral aspects of the consequences of AIDS and the threat of AIDS to people who have positive tests and are involved with persons who have AIDS.

These research findings are published in the usual scientific journals, but the extracts of these are being publicized in a continuing education program for a number of physicians, especially in big cities, such as San Francisco and New York.

Senator INOUYE. At the present time, there is some controversy suggesting that Hispanics and blacks are just as susceptible to AIDS as whites. Do you have any comment to make whether these posters serve any good purpose?

Dr. MACDONALD. I have no official comment at this time. However, I heard on the radio this morning that the posters are going to be removed from those places.

Dr. FRAZIER. I don't know about them, but I feel that any kind of publicity which raises the level of anxiety concerning AIDS, without also providing adequate information, may lead to panic and emotional distress to these individuals. I think that we ought to be very cautious about spreading the word, without also giving all the necessary help that goes with it.

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CSP PHASEOUT

Senator INOUYE. The development of community support systems for the chronically mentally ill is an important effort in preventing homelessness among this population, yet you are proposing to eliminate funding for the CSP Program.

Do you have evidence to indicate that States no longer need assistance in developing strategies for community-based care for the homeless mentally ill?

Dr. MACDONALD. The CSP Program has, in many ways, been a marvelous success in dealing with the problems of deinstitutionalization and the homeless, and has helped States to focus on methods of providing care for those people. It really has worked very well.

The original intent of CSP was as a demonstration model in a 5-year program. All 50 States have now been funded, and while it is our feeling that the CSP efforts are important, compared to State budgets the Federal contribution is a relatively small amount. An average CSP grant is approximately $125,000. In addition, this agency often struggles with the transition from an agency which was providing direct services to an agency that is primarily research-oriented. At this time it really does not fit with the research mission of ADAMHA to be a provider of services through the CSP Program.

Our position does not imply that we don't care about the chronically mentally ill. Dr. Frazier and I have visited homeless shelters here, and we have eaten in soup kitchens. We have spent a lot of time exploring those issues, and we consider them important, but not really relevant to the ADAMHA mission.

Senator INOUYE. At the present time, four States maintain a demonstration project. What effect will your budget cuts have on these four States?

Dr. MACDONALD. The continuation costs of CSP research projects will be eliminated next year. I am not sure how that will affect the four States individually.

Senator INOUYE. The subcommittee has several other questions, but I would like to now call upon my distinguished colleague, Senator Domenici.

SERIOUS MENTAL ILLNESS

Senator DOMENICI. Thank you very much, Mr. Chairman.

I am pleased to be here. I do want to say, as a member of the subcommittee, that I have a very serious and growing concern about our country's efforts in terms of serious mental illness. I think we have been, as a nation, hiding it for too long. I am prepared to be part of efforts to put it on the table before the American people, because I think it is one of the most debilitating of all the diseases around.

Serious mental illness in our country is probably doing more harm, costing more money, and having more of an effect on families and individuals, than many of the diseases that we put front and center, including cancer. We shouldn't ignore mental illness in terms of its cost

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to society, and the lack of success on the part of our Nation in doing something about it.

I want that known right up front. I am certainly one who is looked to to cut Federal deficits, but clearly I don't see any area that we ought to do more in, and that we have done less in, in terms of the relative importance and relative seriousness of the problem, as in the whole area of mental illness. It is not an area that I am going to be interested in balancing the budget on, I assure you.

We have done some good in the last couple of years in increasing funding for these programs. I hope that we have given some encouragement to those who are running the programs by offering them some continuity.

I am also concerned, Mr. Chairman, about the nature of the research. This is not to criticize anyone here. It is certainly not any criticism of Dr. Frazier. Clearly we have to stimulate some genuine interest on the part of the talent in this country to get involved in research. Success will come when the really talented people coming out of our medical schools and the Ph.D's find mental illness an area that is very fruitful for research. The way we have been handling research for mental illness, we are not close to that.

I don't think that very many of our very talented minds will get into it until we provide the stimulus, and they know that it is going to be exciting research that has a chance of success. So I am not going to be one who rubberstamps what you all are doing. I hope that I find time to be a constructive critic. Neither do I think that the way to get it done is to substantially reduce the funding.

Some of the small programs turn out to be very important. In my opinion, the CSP Program is an excellent experiment on the part of our National Government. I think we know a little bit more now about the lack of help out there for the homeless and for people with mental illnesses, and why we have so many more of them roaming our streets. We think that it is because we have cut the programs, but we are not sure of that. It may be that deinstitutionalization is one of the major contributors.

It certainly doesn't mean that we can cut back on programs like the CSP. Frankly, I don't think the States will pick that program up, Dr. Macdonald, even though you responded that it is small. I think that the States are going to be so hard pressed that they are not going to fund those programs out of their block grant. Frankly, I intend to inquire into that, because I think that it would be terrible, after a successful experiment, to have no more of that community-support program out there. It ought to be built on, in my opinion, not reduced.

CONTINUING CSP EFFORTS

Do any of you really think that the States are going to keep that going? Do you, Dr. Frazier, or Dr. Macdonald, even though it is small? Don't you have some concern that the States may well stop that one small program, considering the myriad of things that they are going to be asked to do with their block grant?

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Dr. MACDONALD. I would guess, Senator, that that will vary from State to State. I think that some of the things the program has done have demonstrated its effectiveness. One of the things it did was to focus on the problem, and I think we have done that well. In looking at the various States, a number of them have identified a planning component to look at problems of the chronically mentally ill.

While the response will vary from State to State, the concept's demonstrated effectiveness, I think, will continue to drive States to fund CSP programs.

Senator DOMENICI. We have no way of really knowing that, I guess, at this point, do we? Your judgment is as good as someone else's, but we don't know the answer.

Dr. MACDONALD. That is true.

MENTAL HEALTH PRIORITY AREAS

Senator DOMENICI. Let me just ask Dr. Frazier one general question.

You have heard my observation about the seriousness of mental illness in our country, and how it is a user of hospital beds, a depriver of work opportunities, and thus a huge diminisher of productivity. You are new in your job, but could you briefly give us your views on what we ought to be doing that we are not doing, and what you have in mind as you proceed with your new assignment?

Dr. FRAZIER. Yes, Senator Domenici. I feel very strongly that we need to target our efforts toward the particular problems in the mental health area. Some of the problem areas have to do with vocational rehabilitation and training of individuals who have chronic mental illness. We need also to extend our epidemiological surveys to find the exact nature of this population. We must find out how many of the homeless who are mentally ill and on the streets, how many have been treated, how many need treatment, and how many need other kinds of help. All of this is in addition to treatment for their illness, making the most of their vocational aptitudes, and determining the kinds of interventions which may be helpful.

We have whole families on the street with a mentally ill parent, and we have to look at that situation.

The interventions have not been tested in the homeless chronic mentally ill population very effectively. So we are looking very carefully at some target areas in certain cities with some of our applied research orientation.

In other words, I agree with your statement that we don't know the nature of this population very well. We need to explore it much more carefully, and find interventions which will be effective. Then we must test the effectiveness of these interventions over time.

STATUS OF RESEARCH EFFORTS

Senator DOMENICI. Doctor, how about our research into the causes of, and cures for, serious mental illness? How would you categorize the present status of this research, and how do you plan to move in those particular areas?

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Dr. FRAZIER. We have very extensive efforts in the research of the major psychoses, with special evidence of really important findings in the affective disorders, the depressions, the manias, the highs and the lows. We have an extensive effort for research in schizophrenia which is the major mental illness which requires our attention and our approach.

The researchers are essentially biomedical in their main thrust at the present time. However, we do have psychosocial kinds of treatments which are being researched to determine their effectiveness and their applicability to particular populations.

We are also looking at the problems of children's mental disorders, the development of psychosis, the development of depressions in children, the early development of childhood schizophrenia and of autism. We are looking at the interventions, and we are looking at the basic causes. We are looking at the effect on the families in the biological, the psychological, and the psychosocial spheres.

Senator DOMENICI. Thank you very much.

Thank you, Mr. Chairman.

Dr. MACDONALD. If I could make two comments on your opening statement, Senator.

Senator DOMENICI. Please.

Dr. MACDONALD. One of the things that you brought up that I think is most important is the issue of the stigma that surrounds all three of our program areas. It is a concern of all of us that there are a fair number of people in this country who believe that all three disorders are related to morality, and the inability of people to pull themselves up by their bootstraps. That is a great problem that we all share.

RESEARCH QUALITY

The other is in regard to your comments about research. I don't think that you were negating some of the accomplishments that have occurred, but I feel that we should point out that what has been done has really been superior. We have had a couple of Nobel prize winners as ADAMHA scientists or grantees. This year we may have another. The quality of our research has been absolutely outstanding. Our priority scores are excellent and we are proud of those.

What we must do and what you are addressing in your question is that we must continually look at our priorities and decide where the most productive research will be, and change and modify our strategy accordingly. I don't want to leave the impression that our efforts have not been distinguished.

Senator DOMENICI. I didn't mean that. I guess I am just a little bit hard on it. I just think that we can do better. I am not saying that we can't and clearly, from time to time, we need your advice to make sure that we don't do anything up here to slow the momentum. I am convinced that if the American people at large knew as much about serious mental illness as they do about cancer, we would be further along.

That is not to disparage your work. I just honestly believe that it is far more serious than we have led everybody in this country to believe

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and understand. It is far less tangible than the Cancer Institute's job, and its funding. Clearly cancer is a major disease. We have spent a lot of money there, and we have had some success.

I am thinking that the American people wouldn't let us get by as a great Nation with the amount of success on treating mental illness, if they really knew the facts. It is the sort of thing that we don't like to talk about. The stigma is bad, and a lot of people play on the stigma. There are a lot of funny stories told about the stigma. People even produce funny cards about it, make fun of it, play on words and on paranoia. I don't think that they would be doing that for the other diseases, and mental illness is just as much a disease.

It just angers me from time to time, and I intend to stay on it to see what I can do. When I can get that budget out of the way, I will be a help to you here, Senator, in what you are trying to do on this committee.

Senator PROXMIRE. Thank you, Senator Domenici.

I might say, you couldn't have a better friend than Senator Domenici. He is Mr. Scrooge as far as the budget is concerned. He will do anything he can to hold down spending. So if he comes forward and says that he thinks we ought to put more resources into ADAMHA, you really have an important champion.

SCHIZOPHRENIA RESEARCH SUPPORT

Dr. Frazier, the National Institute on Mental Health, apropos of your answer to Senator Domenici, seems to be cutting back in its research into schizophrenic disorders. Last year, your justification indicated that you planned to spend $18,237,000 in 1984 and $19 million in 1985 on extramural research into schizophrenic disorders. However, this year your justification shows that you spent only $11,178,000, not $18 but $11 million, on such research in 1984, and plan to spend not $19 million but $12,404,000 in 1985.

Can you tell us why you have decided to cut your support for research into schizophrenic disorders by one-third below your initial estimate?

Dr. FRAZIER. It is a different method of accounting. In fact, we have not reduced our research into schizophrenia. Much of the same research that had previously been identified as schizophrenic research has now been counted as basic research.

Senator PROXMIRE. So the research is different.

Dr. FRAZIER. It is a difference in accounting but not in actual level of effort.

Senator PROXMIRE. It may be a difference in accounting, but the table designations are exactly the same so you appear to have an actual reduction in spending. You should at least have footnoted the table.

Dr. FRAZIER. In 1984, the actual was $11.2 million and in 1985 it is $12.4 million. It has gone up.

Senator PROXMIRE. I am referring to page 33 of last year's justification, which shows you planned to spend $18 million in 1984 and $19 million in 1985.

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Dr. FRAZIER. That is last year.

Senator PROXMIRE. That is right, we are talking about last year's estimates.

Dr. FRAZIER. We have revised the accounting method.

Senator PROXMIRE. Let me ask Mr. van der Voort to follow up on that.

Mr. VAN DER VOORT. How have you revised the accounting method?

Dr. MACDONALD. Dr. Frazier's point was that much of what we considered schizophrenia research previously, we now put in the basic brain and behavior category.

Mr. VAN DER VOORT. That is a rather vague explanation for a change in the ground rules.

Dr. MACDONALD. Many of the basic brain studies relate to schizophrenia.

Senator PROXMIRE. Can you do this, can you make these figures comparable by putting them on the same basis for just this one year so that we can see exactly what has happened? Maybe you have increased spending on research into schizophrenia. Have you increased spending or is it the same?

Dr. MACDONALD. There is a slight increase. I would like to point out that Dr. Frazier and all of us consider schizophrenia right at the top of our research priorities, without question.

I don't know if we can give you the number today, but we can for the record.

Senator PROXMIRE. I will be glad to have that information for the record.

[The information follows:]

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Extramural Research Related to Schizophrenia
Reconcilation of 1984 and 1985 Obligations
as Reported in 1985 and 1986 Budgets

The variance between 1984 and 1985 dollar levels reported for schizophrenia and other mental health extramural research funding priorities, as reported in the 1985 and 1986 budgets, results from three factors:

1. Revision of the method by which grant dollars are attributed to each mental health problem area. This is the most significant factor of change, and will be explained more fully in the material which follows;

2. The addition of Congressional increases which were not approved until after submission of the 1985 President's budget; and

3. The impact of proposed FY 1985 rescissions pursuant to the Deficit Reduction Act of 1984; and projected lapses of funds in accordance with provisions of the Treasury-Postal Service Appropriation Act of 1985.

Revisions to the Method of Reporting

With the exception of Congressional increases and the proposed rescissions and lapses cited above, the NIMH has maintained essentially the same level of effort as planned, for schizophrenia and other priorities, in 1984 and 1985. There has, however, been a significant change in our method of ascribing costs to these programs.

Individual research grants frequently relate to two or more of the priority areas displayed in our Congressional justifications. However, the official accounting system does not subdivide costs below the single grant level, since its function is to allocate costs and awards by mechanism, organization and type of award. Moreover, our ten priority areas cut across all of our extramural research organizations, so that the standard accounting classifications do not match the priority categories. As a result, a grant which supports the early identification of schizophrenia in children is potentially reportable under prevention, schizophrenia, or childhood mental health disorders.

When developing the 1984 and 1985 budgets, NIMH used a two-step process to allocate its costs by priority area. First, our ten research priorities were arranged in a hierarchical order: (1) basic studies of brain and behavior; (2) schizophrenia; (3) depression and manic depressive illness; (4) aging; (5) childhood disorders; (6) anxiety; (7) stress and psychosomatic disorders; (8) epidemiology; (9) prevention; and (10) other mental health areas. Second, this sequence was applied to each grant, and the entire dollar value of the grant was attributed to the first subject covered by any component of the project. Because a large number of grants had some portion of effort devoted to schizophrenia, and because schizophrenia was first in the sequence of priorities, this category was second only to basic brain and behavior research in size.

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Approximately one year ago, after the 1985 budget was submitted, the reporting system was changed. The 1986 budget reflects a distribution which allocates the cost of each grant to as many as three priority areas, provided that at least 30 percent of the value of the grant pertains to a given area. The new formula produced changes throughout our priority system; however, the greatest single change was to remove approximately $8.7 million in inappropriate 1985 costs from schizophrenia, and distribute the funds among depression, childhood disorders, and basis studies of brain and behavior. Comparable changes occurred in the recalculated 1984 budget. We regard the current system as far more accurate than any method previously used.

The following table summarizes the changes which occurred in the 1984 and 1985 columns of the 1985 and 1986 budgets:

Comparison of 1985 and 1986 Budgets by Priority
(Dollars in thousands)

Priority Area and Fiscal Year	Amount Reflected in 1985 Budget	Changes: Revision of Reporting Method	Changes: Other Actions A/	Amount Reflected in 1986 Budget
FY 1984 Column:				
Schizophrenia.....	$18,237	-$7,083	+$124	$11,278
Depression & manic depressive illness...	14,600	+6,124	+230	20,954
Aging	6,900	-331	+73	6,642
Childhood disorders...	11,000	+2,316	+148	13,464
Anxiety disorders.....	4,500	-670	+43	3,873
Stress & psychosomatic	7,700	-2,457	+58	5,301
Basic brain & behavior	30,500	+4,113	+384	34,997
Epidemiology.....	11,500	+425	+132	12,057
Prevention	10,100	-5,461	+51	4,690
Other M.H. areas.....	5,811	+3,024	+98	8,933
Total, 1984 column..	120,848	—	+1,341	122,189
FY 1985 Column:				
Schizophrenia.....	19,000	-8,719	+2 123	12,404
Depression and manic depressive illness...	15,156	+5,893	+1,576	22,625
Aging	7,100	-754	+1,108	7,454
Childhood disorders...	11,300	+3,219	+1,114	15,633
Anxiety disorders.....	4,700	-659	+561	4,602
Stress & psychomatic..	7,800	-2,732	+965	6,033
Basic brain & behavior	31,200	+5,289	+3,447	39,936
Epidemiology.....	11,600	+408	+1,327	13,335
Prevention	10,200	-6,081	+1,226	5,345
Other M.H. areas.....	5,800	+4,136	+618	10,554
Total, 1985 column..	123,856	—	+14,065	137,921

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(Dollars in thousands)

Priority Area and Fiscal Year	Amount Reflected in 1985 Budget	Changes: Revision of Reporting Method	Changes: Other Actions A/	Amount Reflected in 1986 Budget
FY 1986 Column: B/				
Schizophrenia	20,545	-8,456	—	12,089
Depression and manic depressive illness	16,412	+5,715	—	22,127
Aging	7,968	-731	—	7,237
Childhood disorders	11,961	+3,122	—	15,083
Anxiety	5,060	-639	—	4,421
Stress & psychosomatic	8,493	-2,650	—	5,843
Basic brain & behavior	33,523	+5,129	—	38,652
Epidemiology	12,585	+396	—	12,981
Prevention	11,071	-5,897	—	5,174
Other M.H. areas	6,139	+4,011	—	10,150
Total, 1986 column	133,757	—	—	133,757

A/ Other actions include the following: For 1984, +$1,900,000 in Congressional increases and -$559,000 in reprogramming to intramural research; for 1985, +$15,422,000 in Congressional increases and -$1,357,000 in decreases related to the Deficit Reduction Act and Treasury-Postal Service Appropriation Act (Section 515).

B/ The FY 1985 budget did not include a FY 1986 estimate. FY 1986 data shown under "Amount Reflected in 1985 Budget", comprise the 1986 budget estimates distributed under the priority allocation formula in effect at the time the 1984 and 1985 budgets were developed. This is included in order to make possible a comparison of all three fiscal years.

ALZHEIMER'S DISEASE

Senator PROXMIRE. In your prepared opening statement, you say that you plan to explore innovative treatments for Alzheimer's disease victims. Can you give us a little more detail and tell us what innovative treatments you plan to explore?

Dr. MACDONALD. I am going to defer that one to Dr. Frazier also, if I may.

Dr. FRAZIER. The treatment for Alzheimer's disease which we are exploring has to do with the introduction of the drug physostigmine, which is used in combination with the cholinergic agent, lecithin. This is being tried in certain selected centers, and some of our Alzheimer research projects. There has been some memory improvement with physostigmine, but there has not been very much marked overall behavioral improvement. It is too early to come to a conclusion.

I don't want to build false hope around it. I just want to tell you that we do not consider Alzheimer's disease to be irreversible. We have people who are concentrating their efforts on the development of new treatment in this particular area.

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Dr. MACDONALD. There are two other areas, Senator, that are also of importance. One is dealing with the family of the person who has the disorder, where we are stressing the importance of giving them help and teaching them supportive mechanisms.

There is also the relationship of depression to Alzheimer's disease, and it is important that those people who can receive medication to deal with that component of the disease are given it.

COCAINE AND ANTIDEPRESSANTS

Senator PROXMIRE. You indicated in your opening statement, Dr. MacDonald, that cocaine is a very dangerous drug. I understand that antidepressants might prove to be effective in treating cocaine abuse, and that the drug desipramine, in particular, shows great promise.

What work are you supporting in that area?

Dr. MACDONALD. We have conducted a number of studies, and I will have Dr. Pollin comment on this, that have compared antidepressant agents with a mild stimulant. They seem to show that there is improvement in dealing with some of the craving that people who are cocaine addicted have.

Dr. POLLIN. We are just beginning to look at a wide range of new treatment approaches, Senator Proxmire. Early reports by Kleber and Gavin, on the use of a variety of antidepressants have been encouraging. We are actively pursuing that.

We are more encouraged by the fact that during the past year we have begun to understand something about the basis for the fact that cocaine is in some ways the most powerfully addictive drug that we know. We think that out of that new understanding of why the drug is so dangerous, a whole new set of treatment approaches may be developed that will strengthen our ability to deal with this very dangerous problem.

SUPPORT FOR COCAINE RESEARCH

Senator PROXMIRE. Dr. Pollin. Dr. Macdonald indicated in his opening statement that research by your institute has discovered that cocaine could be more dangerous than heroin and other commonly abused drugs. Yet, I note that you have dramatically scaled back your proposed support for extramural research into cocaine and stimulants.

Last year's justifications indicated that you planned to spend $4,900,000 on that program in 1984 and another $5,900,000 in 1985. Maybe this is also a matter of a revision in your accounting methods, but you actually spent $2,048,000 in 1984, and you now plan to spend $2,600,000 in 1985. Why did you decide to cut your projected support for that program in half?

Perhaps, first of all, I should ask if those figures are accurate?

Dr. POLLIN. The change that Dr. Macdonald described is a change that grows out of our increased understanding. We, for the first time, have begun to understand the biochemistry of the brain, work which in the past was limited to clinical areas now is being——

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Senator PROXMIRE. Are my figures correct?

Dr. MACDONALD. On page 61 of the justification, we show an increase in 1984, in 1985, and in 1986.

Senator PROXMIRE. Last year, you showed a much bigger projected budget. This year, you show a dramatically smaller budget. This year's justifications say, "Cocaine and stimulants, fiscal year 1984 actual, $2,048,000, fiscal year 1985 estimate, $2.6 million."

Dr. MACDONALD. And $3.2 million in 1986.

Dr. POLLIN. If I might suggest, Senator Proxmire, that we provide, for the record, a detailed analysis of the way that program broke down in 1984 and 1985, and what we are planning for 1986.

In general, I would say that cocaine is the top new priority, and our planning is to give it the largest percentage increase.

Senator PROXMIRE. Please explain, for the record, why there was a cut in your initial estimates.

Dr. POLLIN. I think the information we will provide for the record will explain the cut.

Dr. MACDONALD. We will do that for the other area, too, Senator Proxmire.

[The information follows:]

COCAINE RESEARCH

Senator Proxmire, your numbers are correct. The amount we actually spent on research on cocaine and stimulants in fiscal year 1984, $2,048,000, is lower than the amount we estimated last year, $4,900,000, and our current estimate for fiscal year 1985, $2,600,000, is lower than the estimate we made last year, $5,900,000. These reductions do not reflect a reduction in the importance we place on research on cocaine, but rather a lowering of our estimate of how quickly we can expand our research program in this area based on the actual numbers of grant applications we received.

As you know, most of our extramural budget is used to support investigator initiated research, that is, projects in which the area of research is proposed by the investigator rather than the Government. Approximately 80 percent of NIDA's extramural budget is allocated to investigator initiated research. And only about 36 percent of this amount can be used for new starts to expand our current program. What we found in fiscal year 1984 was that, in spite of the priority we put on cocaine research, we did not receive enough cocaine related research proposals with satisfactory priority scores to meet our original estimate. In the light of this experience, we revised our fiscal year 1985 estimates downward.

To remedy this problem, we issued a new grant announcement calling for more submissions of cocaine related research proposals. We believe this announcement will stimulate sufficient numbers of high quality proposals to meet our revised estimates. We would like to point out that the increase we are proposing for cocaine research in fiscal year 1986, an increase of 56 percent, is by far the largest increase in any of our research areas.

MISUSE OF PRESCRIPTION DRUGS

Senator PROXMIRE. Dr. Pollin, an article that appeared in the Wall Street Journal last September quoted the National Institute on Drug Abuse as saying that "60 percent of hospital emergency room admissions for drug overdose and 70 percent of drug related deaths are due to prescription drugs." Bonnie Wilford, the head of the American Medical Association's Drug Abuse Unit, was quoted as saying, "Pre-

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scription drugs used to hit the street only when street drugs were scarce. Now there's an actual preference for the prescription product. It has a predictable potency, cheaper price, and lighter penalties for use." One drug mentioned in the article was Diladid, a heroin-like pain killer with a street price of $60 a tablet.

Can you tell us what steps you have taken to curb the misuse of prescription drugs?

Dr. POLLIN. Yes; we have been working with the AMA and individual State drug agencies to curb that particular problem. It is true that drugs like Diladid, which is mentioned there, sometimes are indeed more potent and are used frequently when available by addicts.

However, despite those figures in terms of overdose deaths mentioned, we do continue to feel that in terms of the overall national problem, it is the illicit drugs, and particularly cocaine, which we have to put our greatest priority on in terms of the potential threat if that is not dealt with.

We will be glad to supply detailed descriptions of the work that has been done with prescription drugs, and our feeling that although there may be some increases in drug mentioned, in terms of the severity of that problem, we have achieved significant improvement as compared to where we were 4 or 5 years ago.

Senator PROXMIRE. Do you want to follow up on that?

Mr. VAN DER VOORT. I believe, Dr. Pollin, that you have said that you are putting your emphasis on illegal drugs, although the statistics do seem to indicate that it is legal drugs that are the greatest problem in terms of deaths and emergency room admissions.

Dr. POLLIN. In terms of just the numbers with regard to admissions and overdose deaths, that can be the case, but one has to look at the very, very different level of prevalence that we are dealing with here, and one has to look at rates of increase. Just to take cocaine, again, at this point, we have only one-tenth of 1 percent of current users of cocaine as compared to the current users of legal drugs that can cause a serious problem, and do cause a serious problem.

If we were to lose control of either incidence or prevalence with regard to cocaine, or if the availability of cocaine in terms of price were to decrease, we are convinced, based on its pharmacological effect, that the number of users might rise rapidly to approximate the 50 to 60 million who currently use and have problems with nicotine. If that should be the case, the danger to the country would be almost incomprehensible.

COCAINE MISUSE

Senator PROXMIRE. Senator Domenici just told me, and I think he is absolutely right, that there is an unfortunate lack of public awareness of the dangers of cocaine. Perhaps your organization could help publicize those dangers as dramatically as possible.

Dr. MACDONALD. We would like to work with the press in paying more attention to the fact that this is not a harmless drug.

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Senator PROXMIRE. The drug is considered sort of a classy indicator of upward mobility in some areas, which makes people think that it can't be that bad. Athletes and movie stars use it. Anything that you can do to get your message out will be of great service.

ALCOHOL TREATMENT RESEARCH

Dr. Niven, last year's Senate report on the Labor-HHS-Education appropriations bill included language directing the National Institute on Alcohol Abuse and Alcoholism to go beyond a mere literature search of alcoholism treatment assessment research and to devote a significant portion of its budget to studies of the relative cost effectiveness of varying methods of treatment as applied to patients with differing characteristics. We wanted particular emphasis placed on alternatives to the expensive inpatient treatment emphasized by Medicare.

Can you tell us what research you are currently supporting in that area?

Dr. NIVEN. Yes, Senator, the Institute has indeed pursued the committee's interest, NIAAA's interest, and the field's interest. That interest has actually been heightened by the implementation of the prospective pay system and our struggles to understand the diagnosis related groups as they are applied to alcohol and drug abuse treatment.

We have increased our emphasis on treatment research in the past year, and we intend to increase that again in the next fiscal year. We will have available in the immediate future a treatment handbook series, which is a review of the literature to help researchers who submit treatment outcome research applications to us to become more consistent in the diagnostic instruments that they use so that all studies are more comparable.

We have continued with the——

Senator PROXMIRE. Let me interrupt you, Dr. Niven, to ask you what specific research you are currently supporting in that area.

Dr. NIVEN. The major project that we are funding right now is a joint demonstration project with the Health Care Financing Administration that has been going on for several years. That project will be drawing to a close this year when actual patient admissions to the programs will cease over the next few months, although we will be analyzing and evaluating that data which was collected over the past 5 years.

We have also just completed and gotten reports into the institute, literally in the last 2 weeks, on two treatment outcome studies that we have been doing. The bottom line of one of them being that, indeed, treatment for alcoholism is both inexpensive in terms of the cost to insurers and cost effective. This was a study of one of the Federal Government employees health benefit plans.

The second study dealt with the DRG as applied to alcohol and drug dependence. Jointly, these studies provide support for several fundamental ideas that we have had for a long time—namely, that alcohol dependence is associated with increased medical visits, to both hospitals and doctors, and that the cost of such visits diminishes following treatment.

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SUPPORT FOR TREATMENT ASSESSMENT RESEARCH

Senator PROXMIRE. Let me ask, specifically, how much money you will be spending on alcoholism treatment assessment research in the current fiscal year, and how much you plan to devote to that work in fiscal year 1986?

Dr. NIVEN. I do not have those numbers at my fingertips, but I will be glad to provide them for the record. We do have an increase in our 1986 budget.

Senator PROXMIRE. What treatment assessment research initiatives will you be pursuing in fiscal year 1986?

Dr. NIVEN. The major initiative that we are pursuing right now is simply to continue to stimulate more comparable research proposals, and to improve the methodology being used to evaluate treatment outcome research. Treatment outcome research is methodologically very difficult to do because there are a lot of variables that impact it. We are pulling together a group of experts made up basically of researchers and expert clinicians around the country, to advise and to help us identify key issues and problems in treatment research in order to stimulate high quality treatment research grant applications.

DIETARY GUIDELINES

Senator PROXMIRE. I have just one other question. Last year, Dr. Niven, we talked about some proposed new dietary guidelines to be issued by HHS and the Department of Agriculture that apparently planned to state that no harm is caused by one or two drinks daily, and that two drinks a day may actually be beneficial to nonpregnant adults.

Would you tell us when those guidelines will be coming out?

Dr. NIVEN. Senator, if I might go back to your previous question, my budget officer just handed me a note that says that in fiscal year 1984, the funds spent for treatment research were $4.3 million, and in fiscal year 1986, we plan to spend $5.3 million, a 20-percent increase.

We have had continuing interest in watching the progress of these new dietary guidelines. The advisory committee has not yet finalized its report. Once that report is submitted, we do anticipate having an opportunity to formally comment on it.

ST. ELIZABETHS PATIENT DEATHS

Senator PROXMIRE. The staff suggested that I ask two other questions.

Dr. Frazier, last year, you estimated that there would be 75 patient deaths at St. Elizabeths in 1984 and there were actually 114 deaths. This is an increase of 22 deaths over the death rate in 1983. Is there an explanation for that substantial increase in patient deaths, which exceeded the initial estimate by so much?

Dr. FRAZIER. Senator Proxmire, I don't know the answer to that problem. I am sure that Dr. Prescott who is here from St. Elizabeths might know the answer.

Senator PROXMIRE. Dr. Prescott, would you want to respond to that question?

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Dr. PRESCOTT. Yes, sir.

One of the things that we have to take into consideration in estimating the death rate at St. Elizabeths Hospital is the percentage of the population that is aged, and has not been placed outside of the hospital. As each year goes by, more of these people move into the time of life when their health deteriorates. I will supply that information for the record.

Senator PROXMIRE. Does that explain why your estimates were so far off?

Dr. PRESCOTT. Yes; and I will have to supply that for the record.

[The information follows:]

VARIANCE BETWEEN ACTUAL AND ESTIMATED PATIENT DEATH RATE—FISCAL YEAR 1984

In the 1985 budget request submitted in January 1984, the number of patient deaths at St. Elizabeths Hospital was estimated to be 75 in 1984. The actual number of deaths was 114, or 52 percent over the estimate.

The original fiscal year 1984 estimate presumed that a court-ordered moratorium on the outplacement of patients into District of Columbia facilities would be lifted by April 1, 1984. The moratorium had been ordered pursuant to *Dixon* v. *Heckler*, and reflected the conclusion of the court that there were insufficient alternative facilities to receive patients into the community.

The moratorium was not lifted. As a result older, long-term patients were retained by the hospital while additional ones were admitted. Because this group of patients has the highest statistical risk of death due to old age and physical illness, the number of deaths among persons still on the hospital rolls increased substantially over the original estimate.

It is important to note that there was no increase in the death rate among the total number of patients treated at the hospital in 1984. The variance between the estimated and actual number resulted entirely from the fact that persons in the highest risk group were reportable as hospital patients for approximately half a year longer than anticipated.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator PROXMIRE. Thank you very much. There will be some additional questions submitted for your response for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

APPROPRIATE LEVEL OF RESEARCH

Question. According to my calculations, at the 500 grant award level, you would be funding only 36% of the 1,383 grants you anticipate will be approved for FY 1986. Do you believe this is an appropriate level of research support?

Answer. Yes, we believe that the proposed level of research support recognizes scientific need in that it assures stability in the number of awards available. There has been a great deal of instability in the number of competing awards made by ADAMHA in the last decade, and we are concerned that continuance of this situation might discourage talented investigators from entering, or remaining active in the alcohol, drug abuse and mental health research fields. Our proposed 1986 number of grants will be the third year of support for 500 competing awards, so investigators should have an excellent idea of their chances of successfully competing for an ADAMHA award.

RESEARCH NEED

Question: Is there any evidence of a reduced need for research in the areas of alcohol, drug abuse and mental health?

Answer: We do not believe there is any indication of a reduced need for ADM research. In fact, the evidence shows that recent discoveries made in the alcohol, drug abuse and mental health fields in the areas of neurosciences, prevention of substance abuse, and the effects of behavior on health have helped define and prioritize areas where further research is needed. For example, encouraging results in schizophrenia research within the past years have shown that new information is still needed to better understand the cause of the illness and what role drugs play in its treatment. Similarly, progress made on the treatment of depression, manic illness and Alzheimer's disease must be expanded upon to determine effective drug or other therapies for patients with these illnesses. Finally, research stemming from the discovery of endogenous opiates and the genetic basis of alcoholism promises to provide rapid advances in our understanding of the biological and psychological basis of these illnesses and the development of scientifically sound prevention and treatment techniques.

STAFFING CUTS

Question: How many FTEs do you have at the present time and will a reduction in force be required in order to accomplish this reduction?

Answer: Without consideration of any attrition, our most recent FTE projection for 1985 is 1,571. While the budget now before the Congress requests an operating level of 1,527 FTEs, including 15 for the Cuban-Haitian program, the PHS has authorized an actual operating level of 1,547 FTEs. We do not expect a reduction in force to be required in order to attain this 1,547 level in 1985.

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Question: What is your rate of attrition and will this bring you down to the 1,527 FTE level?

Answer: We are projecting an attrition rate of six percent. This would not get us down to the 1,527 level in 1985; however, it should get us down to the 1,547 level in 1985 and we would reach 1,527 in 1986.

RESTORATION OF INTRAMURAL RESEARCH PROGRAMS

Question. For what purpose were the funds we provided for restoration of Intramural Research Programs at each institute used?

Answer. In all three institutes a large portion of the funds is being used to absorb the full cost of the January, 1985 pay raise. In addition, because positions are being eliminated through attrition, some of the restored money is also being used to pay those employees still on board at the start of the fiscal year. At NIDA the remaining funds are being used to purchase equipment for the newly renovated building in Baltimore, and in NIAAA some will support improvements to the clinical research facilities.

NIMH RESEARCH ON AIDS

Question: NIMH has been supporting research into the mental health aspects of Acquired Immune Deficiency Syndrome (AIDS).

What kinds of research have been conducted thus far, and with what results?

Answer: During FY 1984 NIMH continued and expanded its research support for projects focused on the psychiatric, behavioral and psychosocial aspects of AIDS. This resulted in a portfolio of 14 research projects, totalling $1,204,838. These projects focus on relationships between psychological and behavioral measures to assess mental health status as it relates to AIDS, changes in high risk behavior patterns, as well as studies which supplement ongoing NIH research to correlate behavioral changes with immunological status in large samples over time.

NIMH funding has allowed investigators to develop and improve inventories which measure psychosocial and mental health aspects of AIDS in groups at risk and those with confirmed cases of AIDS. In one study, preliminary results of assessments of the mental health of those at risk suggest the tendency for scores on some measures to be poorer than expected. These tentative results require confirmation and further research to determine their implications. It has been hypothesized that increased levels of depression, helplessness, and anxiety correlate with behavior changes in this population. Such inventories, with modifications, may be valuable in identifying individuals at risk for life-threatening illness beyond the AIDS epidemic. Results may have implications for prevention and therapeutic intervention

An NIMH-supported study is conducting neuropsychological evaluations of AIDS patients to assess differences between psychological reactions to the disease and cerebral problems

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resulting from the disease process which may also affect mood, cognition and behavior. It has been recognized that clinically significant alterations in these functions may be overlooked until patients become disruptive or incapacitated.

The AIDS patient, like patients with other life threatening illnesses, struggles with the fear of imminent death, the necessity for abrupt closure on future plans, and the challenge to maintain a purpose. Knowledge of these factors is necessary to develop effective intervention strategies.

Preliminary results from one longitudinal study indicate some modifications in sexual behavior among those of high risk for AIDS as increased information becomes available concerning transmission patterns.

Question: How are these research findings being translated into services to prevent and treat the psychological problems of those individuals already afflicted with AIDS, as well as those at risk of contracting the disease?

Answer: NIMH is supporting research studies related to psychological risk factors characteristic of individuals who have contracted a terminal illness. Studies which focus on how such individuals learn to cope with death and dying, as well as the stigma of this particular disease, will hopefully provide critical information which can be used to treat people who are currently at risk for AIDS.

Studies are supported which focus on how the immune system responds to severe psychological stress. These should also yield information which can be used to develop treatment programs. NIMH is supporting studies which indicate a deterioration in cognitive functioning characteristic of certain psychiatric disorders. The identification of the course of these neuropsychological problems will permit development of treatment strategies and potential interventions to permit the individual to cope with further deterioration.

Preliminary data indicates that when information of risk factors is provided to individuals at risk (specifically the gay community) there are changes in sexual behavior (e.g., decreases in the number of sexual partners, use of preventive techniques).

Question: What have you done to establish close cooperation between NIMH, CDC, and NIH on the mental health aspects of AIDS?

Answer: NIMH has facilitated cooperation among researchers supported by the NIH who are engaged in large-scale multi-site prospective studies of the course of the disease. Basic behavioral scientists (including psychologists and epidemiologists) have been developing psychological instruments to permit the concurrent assessment of immunological and psychological risk factors related to the disease. Such studies are currently under way at UCLA and the University of Michigan. In addition, the NIAID has involved several NIMH supported scientists on its AIDS advisory board which oversees these multi-center AIDS studies.

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NIMH staff are developing information for both physicians and the individual which is sensitive to the psychological aspects of a positive result on the AIDS blood test, in concert with staff at the NIH and CDC. NIMH staff have also been asked to provide consultation to CDC staff who are developing a curriculum to train health care workers providing services to AIDS patients.

NIMH staff have been asked to collaborate with NHLBI staff to develop and encourage research related to the psychological reactions of individuals who receive a positive result on the HTLV-III blood test.

NIMH researchers will be participating in the International AIDS Conference in Atlanta, April 14-17, which is co-sponsored by NIH, CDC, HRSA and the WHO.

COMMUNITY SUPPORT PROGRAM (CSP) - HOMELESSNESS

Question: The development of the community support systems for the chronically mentally ill is an important effort in preventing homelessness among this population, yet you propose to eliminate funding for the CSP program.

Do you have evidence to indicate that States no longer need assistance in developing strategies for community-based care for the homeless mentally ill?

Answer: The CSP program has directly assisted four States and four urban areas in determining the size and characteristics of the homeless mentally ill population. Six additional States and cities will also receive assistance later this year to demonstrate innovative approaches to involving the homeless mentally ill in services.

The results of these studies will be communicated to all interested States and technical assistance will continue to be provided to them. Assistance provided to date should be sufficient for the entire Nation to draw upon. Services for the homeless mentally ill are a State and local responsibility, and States may elect to use block grant funds for this purpose.

Question: What will be the effect of eliminating this program on the four States currently operating demonstration projects on homelessness?

Answer: Four Community Support Program (CSP) homeless supplements were awarded in fiscal year 1983 to existing CSP projects in Massachusetts, Michigan, California, and Wisconsin. These were funded as one-year, time-limited projects and were designed to obtain better information on the demographic characteristics of the homeless mentally ill. There will be no effect on these projects since they are in their final stages of data collection.

In fiscal year 1985, CSP is planning to award one-year grant supplements to four to six existing CSP projects to develop and improve innovative approaches to service delivery for the homeless

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mentally ill. If the CSP program is eliminated in FY 1986, these will already be completed.

Question: Are you proposing to provide shelter workers any special training in meeting the mental health needs of the homeless?

Answer: We have no plans to provide special training to shelter workers. However, in fiscal year 1985, the Community Support Program (CSP) will be making one-year supplements to four to six State grants. If the States see it as a high priority, these States will be able to use these funds to provide shelter workers with special training in identifying and working with the homeless mentally ill.

NIMH CLINICAL TRAINING

Question: In your response to the GAO report entitled "Effectiveness of Mental Health Clinical Training Cannot be Evaluated," NIMH study groups have estimated that an additional 19 staff and $3.5 million would be needed to collect and analyze the necessary data to determine whether Congressional priorities are being met, and that mental health supply and distribution problems are being addressed. Nonetheless, no funds are being requested for this purpose.

Assuming that the Clinical Training Program is continued, do you agree that the development of this data base would be useful to NIMH and the Congress in determining where to target clinical training funds?

Answer: We believe that an investment of this size would be of marginal value. It is expensive and burdensome to obtain these data, and despite the investment in continually updating the information, we would still not have important correlative data on whether jobs existed in shortage areas. Traditional sample surveys would not suffice for an undertaking of this size. An accurate, current data base would need to be maintained and the upkeep of this base would entail substantial reporting burdens for the States, as well as the public generally. Moreover, NIMH would not be able to place people in shortage areas or subsidize their salaries. We believe that it is better to rely on market forces to attract professionals into areas needing their services, particularly since there seems to be no overall shortage of mental health professionals.

MENTAL HEALTH SERVICES PLANNING COUNCILS

Question: The 1984 amendments authorize each State to establish a Mental Health Services Planning Council to advocate for mentally ill persons and to monitor, review and evaluate at least annually the allocation and adequacy of mental health services within the State.

Which States have elected to establish these planning councils, and what activities have they undertaken?

Answer: Some States already have mental health services planning councils independent of the new Federal legislation. States can use new project grant money to pay for establishing these councils. We will not know how many States choose to request

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planning grant funds until all of the grant applications have been received and reviewed. This will take place during the month of April.

Question: Have any States undertaken advocacy programs for institutionalized mentally ill persons under this authority?

Answer: No, not under this planning authority. However, States have undertaken advocacy programs for institutionalized mentally ill persons under the Community Support Program because this program is specifically directed at improving services for the mentally ill in the community.

INTERAGENCY AGREEMENT WITH HCFA

Question: Since 1969, through an interagency agreement between the Health Care Financing Administration and NIMH, consultants hired by NIMH have surveyed psychiatric hospitals certified under the Medicare program to determine whether active treatment is being provided to residents of those facilities. That agreement was terminated as of January 1, 1985.

What is the reason for termination of this agreement?

Answer: Within the Public Health Service, it is the policy to transfer full time equivalent (FTE) ceilings, as well as funds, when one agency contracts with another for the performance of a service. The purpose of this policy is to insure that the performing agency does not have to curtail its own operations in order to perform services for another. The Health Care and Financing Administration advised us that because of its own ceiling limitations, it would not be able to transfer the necessary FTEs. We were not able to absorb this function within our own ceiling. The FTE requirement for the conduct of Medicare surveys has increased from 1.8 FTE for coverage of 12 hospitals in 1970, to 11.0 FTEs for coverage of 233 hospitals in 1984. Accordingly, we were obliged to terminate our agreement with HCFA on December 31, 1984. We understand that HCFA will be continuing this program through a contract with the private sector.

Question: What is your understanding of the extent to which the former NIMH consultants will continue to participate in these surveys?

Answer: The Health Care Financing Administration (HCFA) clearly recognized the contributions and need for continuation of the role of former NIMH consultants in the conduct of psychiatric hospital surveys. Last September, these consultants were sent a letter, signed jointly by NIMH and HCFA, asking them to continue their services under a new contractual arrangement administered by HCFA.

Question: What personnel and financial resources were required to carry out these surveys in fiscal year 1984?

Answer: NIMH dedicated 11 full-time equivalents to these surveys in 1984. The total cost of the operation was $546,000, all of which was reimbursed by the Health Care Financing Administration.

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Question: Is there any reason to believe that the cost of these surveys will increase now that this agreement has been terminated?

Answer: Although the actual cost of the surveys can only be obtained from HCFA, it is our understanding that the cost will be essentially the same.

Question: Does termination of this agreement mean that you are satisfied that adequate active treatment is being provided residents of psychiatric facilities?

Answer: The termination of this agreement is not at all related to our level of satisfaction with psychiatric treatment. The locus of responsibility and method of financing have changed; but the surveys themselves will continue. The termination of this particular agreement should not be viewed as an indication that there is no longer a need for the surveys. Our past collaborative effort with HCFA has been recognized as a valuable aid in improving the quality of treatment and care in psychiatric hospitals.

In the final analysis, HCFA has always had the responsibility for ensuring that psychiatric facilities comply with certification standards to receive Federal funds, and we are comfortable that they will continue to administer and monitor the program to meet the full legal and regulatory requirements.

TEENAGE SUICIDE

Question: The problem of teenage suicide has reached alarming proportions, with suicide now the second leading cause of death among young people.

Are we in fact seeing an "epidemic" of teenage suicides, as media reports would lead us to believe?

Answer: While "epidemic" may perhaps be too strong a term, suicide is a major and devastating public health problem and it is increasing at a dramatic rate. In the United States suicide is the tenth leading cause of death for adults and the third leading cause of death for adolescents. A conservative estimate is that there are 200,000 suicide attempts and 30,000 completed suicides in the United States each year. This number is assumed to be a minimal estimate since suicide is heavily underreported because of its social stigma. For example, many single motor car accidents and homicides may, in fact, be suicides.

Over the past 30 years, the United States suicide rate for people 15 to 24 years of age has increased dramatically from 4.1 per 100,000 in the mid-1950's to 12.5 per 100,000 in 1980. As a consequence, suicide moved from the fifth leading cause of death in this age group in 1960 to the third leading cause in 1981. Research data also indicate that suicide is the second leading cause of death among college students. Between 1970 and 1978, 39,011 United States residents 15 to 24 years of age committed suicide. During the same

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period, the suicide rate for this age group increased 41 percent while the rate for the rest of the population remained stable.

Another characteristic of the current suicide problem merits serious concern. "Suicide clusters" are occurring at an increasing rate among adolescents. The term, "suicide cluster," refers to the phenomenon of one suicide appearing to trigger several other suicides in a group, such as a school or community. Very little is known about this apparent contagion effect of suicide among adolescents. Suicide clusters have recently occurred in Plano, Texas, in Westchester County, New York, and in Minnesota.

The trend of increasing rates of suicide among adolescents and young adults has been unremitting since 1950. There is no reason to believe that this will change in the foreseeable future until we improve our understanding of why suicide occurs and learn how to prevent this tragic public health problem.

Question: Are there any local programs that have been successful in preventing teenage suicide?

Answer: Currently, the most effective strategy for prevention of suicide is the early detection and appropriate treatment of depression, substance abuse, and other psychiatric disorders. In order to foster earlier detection and more effective treatment, more comprehensive education is needed for individuals at high suicidal risk, their families and loved ones, primary health care physicians, and other health care providers and mental health specialists.

Specialized educational programs are being tried in many locations. Recently, State legislatures in California and Florida have mandated the teaching of suicide prevention education in high school curricula. There is, as yet, no research available evaluating the type and effects of such curricula on young people.

The preventive effectiveness of suicide hotlines and crisis centers has yet to be systematically shown. Yet, this lack of evidence should not be interpreted to mean that hotlines and centers are ineffective. It is unclear that people who contact suicide hotlines are those individuals at highest risk for completing suicide. Further research is needed to clarify what populations utilize these services and what services are offered, and to evaluate the effectiveness of interventions offered.

SUICIDE RESEARCH

Question: Is NIMH supporting any research or demonstration projects toward the goal of understanding and reducing the incidence of suicide?

Answer: The NIMH has established a Suicide Research Unit in the extramural research program to support research related to suicide, and to disseminate information to practitioners and the public about the causes and prevention of suicide. Because of the increase in teenage suicide, this topic is a priority concern of the Suicide Research Unit.

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The Institute also supports suicide research in the intramural research program, studying possible biological markers for suicide, familial factors, and alcohol abuse and suicide.

Several conferences and workshops on suicide have been held or are planned by the Institute. A workshop on prevention research in suicide and affective disorders among adolescents and young adults was held in December 1982. A series of workshops on the contagion effect in adolescent suicide, prevention of suicide, and treatment strategies for suicidal adolescents is planned for FY 1985 and FY 1986. These workshops will summarize our current state of knowledge about teenage suicide and identify areas of further research need.

At the present time, major research efforts are underway in the NIMH Intramural Research Program to understand teenage suicide. In addition, the Institute hopes to undertake increased research on the etiology, treatment, and prevention of those at risk for suicide.

The Institute spent $1.2 million for research on youth suicide in 1984. We expect to spend $1.4 million in 1985 and $1.7 million in 1986.

DRUG ABUSE PREVENTION AND TREATMENT RESEARCH

Question: Your budget justification for the National Institute on Drug Abuse states on page 56 that "Our hopes for success in the development of better prevention and treatment programs have never been higher." Yet your own research indicates an increase in the use of cocaine and other substances such as PCP. What is the basis for this seemingly over-optimistic assessment?

Answer: Although over the past several years we have seen a greater incidence of the severe consequences of cocaine use, this represents only one facet of overall drug use trends. As a number of other factors show a very positive trend, we feel justified in the optimism we expressed. Not least of these is the success that has been evident in the continuing lowering of drug use among youth. Coupled with our increased knowledge of what does and does not work in the treatment and prevention of drug use, we are confident that this positive outlook towards the improvement of success in the treatment and prevention of drug use is well founded.

Our basic research program has made tremendous progress over the last ten years in understanding, not only how drugs affect the working of the brain, but how the brain itself works. The discoveries by NIDA grantees of endogenous opiates and their associated receptors revolutionized our understanding of the brain and put drug abuse research into the forefront of the neurosciences. Recent work, which has focused on the mapping of neural circuits within the brain and identifying their functional significance, has put us in a position where we can begin to expect practical applications of our basic research efforts in the near future.

For example, a new drug developed by NIDA for the treatment of narcotic abuse, naltrexone, was recently approved for treatment. This drug, a narcotic antagonist, offers several advantages over methadone for the treatment of some narcotic abusers. With the

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recent advancements that have been made in our understanding of the brain, it may soon be possible to develop even more effective drugs. There is evidence to suggest, for example, that a wide range of drugs, including narcotics, cocaine, and tobacco, all produce their rewarding effects by stimulating a dopaminergic circuits within a particular part of the brain. It may be possible, therefore, to develop a single drug which, by inhibiting the stimulation of this particular part of the brain, would block the rewarding effects of a wide variety of drugs.

Another area of our research program which may soon have practical payoffs concerns differences in an individual's vulnerability to drug abuse. It is well known that not all people exposed to drugs try them, that only a small portion of those who try them go on to regular use, and that only a small portion of those who use them regularly go on to compulsive use. If we could understand why this is so, why some people appear more vulnerable to drug abuse than others, it would be possible to develop much more effective prevention and treatment programs.

Part of this effort consists of basic research which in concentrated on the biological bases of drug abuse. One hypothesis under study is that some people may be more vulnerable to drug abuse because of defects in their bodies' ability to produce or use certain neurotransmitters. It may be, for example, that some narcotic abusers use narcotics to overcome defects in their bodies' ability to synthesis or use endorphins and enkephalins much in the same way that diabetics must use insulin. If confirmed, it may be possible to develop tests which could be used to predict an individual's predisposition to certain forms of drug abuse and take remedial action before the drug abuse problem develops.

A second part of this effort has concentrated on epidemiological studies to determine risk factors associated with drug abuse. This effort, in addition to looking at biological factors, has also studied various psychological, cultural and sociological factors which may influence drug use. It has focused on studies of individuals who have been able to resist the temptations of drug use as well as those who have proven more susceptible. We believe this research, which is still in its early stages, will allow us to understand much more precisely why some people are more likely than others to abuse drugs, and, therefore, to both better target our prevention efforts toward them and make them more effective as well.

We have also made progress in our research on the treatment of drug abusers. Over the last several years we have placed increased attention on developing ways of identifying the particular mix of possible treatment regimens that will be most effective for particular drug abusers. The results of this research have been distributed to treatment programs and are being used.

Finally, the results of our prevention research program are providing us with information that will make it possible to develop more effective drug abuse prevention programs. In the past, most drug abuse prevention programs were based on the assumption that youth abused drugs because they lacked knowledge about the consequences of drug use. Research conducted over the last several years has shown that this assumption is not correct. Youth use drugs for a variety of psychological, social and environmental

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factors, and, to be successful, prevention programs must address these factors. NIDA's recent efforts have focused on the evaluation of school-based, family, and community prevention programs. Several of these programs have been found to be especially promissing and will soon be tested in larger and more varied settings. If they prove effective in these settings, they will provide a model for effective prevention programs that can be replicated throughout the country.

It is the convergence of these research programs that has sparked our optimism about the future of drug abuse prevention and treatment. Our optimism is also based on overall drug use trends. The information below is from the most recent High School Senior Survey. The figures represent what is called "Thirty day prevalence", i.e. the percent of seniors who have used the drug at least once in the last thirty days. This is considered one of the more important measures of drug use.

Percent of High School Seniors Who Used Drugs in the Last Thirty Days

	Class of									
	1975	1976	1977	1978	1979	1980	1981	1982	1983	1984
Marijuana	27.1	32.2	35.4	37.1	36.5	33.7	31.6	28.5	27.0	25.2
Inhalants	NA	0.9	1.3	1.5	1.7	1.4	1.5	1.5	1.7	1.9
Halluc	4.7	3.4	4.1	3.9	4.0	3.7	3.7	3.4	2.8	2.6
(PCP)	(NA)	(NA)	(NA)	(NA)	(2.4)	(1.4)	(1.4)	(1.0)	(1.3)	(1.0)
Cocaine	1.9	2.0	2.9	3.9	5.7	5.2	5.8	5.0	4.9	5.8
Heroin	0.4	0.2	0.3	0.3	0.2	0.2	0.2	0.2	0.2	0.3
Stimulants	8.5	7.7	8.8	8.7	9.9	12.1	15.8	13.7	12.4	NA
Sedatives	5.4	4.5	5.1	4.2	4.4	4.8	4.6	3.4	3.0	2.3
Tranquil	4.1	4.0	4.6	3.4	3.7	3.1	2.7	2.4	2.5	2.1
Alcohol	68.2	68.3	71.2	72.1	71.8	72.0	70.7	69.7	69.4	67.2
Cigarettes	36.7	38.8	38.4	36.7	34.4	30.5	29.4	30.0	30.3	29.3

As you can see, levels of use for most drugs peaked in 1978 and 1979, and have declined somewhat since. These declining trends are clearly the result of a number of factors. We believe, however, that the efforts we have made to collect and distribute reliable information on the hazards of drug use and the development of our peer pressure resistance prevention programs are at least partially responsible for these changes. This belief is based on the following information, which comes from the same survey.

This first chart displays the percent of high school seniors answering "great risk" to the questions "How much do you think people risk harming themselves -- physically or in other ways --, if they..."

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Trends in the Perceived Harmfulness of Drugs
Percent saying "great risk"

	Class of 1975	1976	1977	1978	1979	1980	1981	1982	1983	1984
Smoke marijuana regularly	43.3	38.6	36.4	34.9	42.0	50.4	57.6	60.4	62.8	66.9
Take cocaine regularly	73.1	72.3	68.2	68.2	69.5	69.2	71.2	73.0	74.3	78.8
Smoke one or more packs of cigarettes per day	51.3	56.4	58.4	59.0	63.0	63.7	63.3	60.5	61.2	63.8

The next chart displays trends in the approval of drug use by high school seniors. The figures represent the percent responding that they "disapprove" to the question "Do you disapprove of people -- who are 18 or older -- doing each of the following?"

Trends in Proportions Disapproving of Drug Use
Percent "disapproving"

	Class of 1975	1976	1977	1978	1979	1980	1981	1982	1983	1984
Smoke marijuana regularly	71.9	69.5	65.5	67.5	69.2	74.6	77.4	80.6	82.5	84.7
Take cocaine regularly	93.3	93.9	92.1	91.9	90.8	91.1	90.7	91.5	93.2	94.5
Smoke one or more packs of cigarettes per day	67.5	65.9	66.4	67.0	70.3	70.8	69.9	69.4	70.8	73.0

What this information shows is that at the same time levels of use of these drugs was declining, the perceived harmfulness and the number of seniors disapproving of their use was increasing. We believe that the change in levels of use is the result of these changes in attitudes, and that these changes in attitudes are, at least partially, the results of our prevention efforts.

With respect to cocaine and PCP, the information available does not show, nationally, a significant increase in the numbers of people using these drugs. What we have noted, and are very concerned about, has been an increase in the adverse reactions to the use of these drugs. This is particularly true of cocaine. As we mentioned in the budget, the number of people admitted yearly to emergency rooms following cocaine use, as reported by the Drug Abuse Warning Network, increased almost 300 percent in five years between 1979 and 1984. This increase in adverse health consequences appears to be due more to changes in the way people are using the drug rather than in changes in the numbers of people using it.

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IOM STUDY

Question. The Institute of Medicine of the National Academy of Sciences has recently released its report summarizing progress in the nation's understanding, preventing, and treating mental and addictive disorders and highlighting some promising directions for future research advances. The IOM suggests that the economic consequences of the disorders under the ADAMHA purview are comparable to those for heart disease and cancer and concludes that "the amount of research on the disorders and health-related behaviors in the ADAMHA domain is much too low, given their enormous costs to society...support for ADAMHA research and research training should undergo an orderly increase over the next five years." What is your reaction to the findings of the IOM study and what steps has the agency taken to incorporate the findings into research policy?

Answer. We have not to date taken any steps to incorporate specific IOM findings into our research policy. However, the report has received wide circulation among ADAMHA staff as well as among individuals prominent in the ADM research fields. We presently have this work under review and will be preparing a response to its recommendations.

To date, the IOM staff and IOM members instrumental in the preparation of this paper have presented their report to our Institute Advisory Councils. They have also met with interested staff at a Congressional briefing on February 25 and the following day they met with the Administrator and the three Institute Directors to discuss the findings and recommendations of their report. Following that meeting the chairman of the IOM preparation panel for this report, Jack D. Barchas, M.D., Department of Psychiatry and Behavioral Sciences, Stanford University School of Medicine, was invited to join agency staff in late March for an agency science retreat where the IOM report was discussed more fully.

RESEARCH TRAINING

Question. The FY 1986 budget requests $1,500,000 each for alcohol and drug abuse research training, as compared to $18,000,000 for mental health research training. Will these levels adequately support the need for research trainees in these fields?

Answer. These levels will provide an adequate amount of support for trainees in the alcohol and drug abuse fields for 1986.

Question. If not, is there evidence that non-governmental entities are meeting this need?

Answer. We have no specific information on the extent to which non-governmental entities may be meeting these needs, but we believe that there is little private support for such training.

Question. Do you anticipate that there will be a shortage of qualified researchers in alcohol and drug abuse in the next several years? In 10 or 15 years?

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Answer. We believe the need for more trained researchers in these fields will continue in the next several years and in the decades ahead. There are abundent, emerging scientific opportunities which hold great promise for addressing these major public health problems. Areas of special promise include: neuropharmacological and clinical effects of alcohol, biochemistry of human alcohol metabolism and genetics, assessment of medical consequences and correlates of alcohol and drug abuse, studies of opiate receptors and sites of action and the epidemiology of drug use and abuse. In addition to the training of new investigators, it is hoped that established workers will move into these fields as they mature and develop.

SEH MANAGEMENT IMPROVEMENTS

Question: What improvements are being made in cost control, management of services delivered, and financial management practices at St. Elizabeths?

Answer: Management initiatives are being taken in the following areas:

- The Hospital is continuing its review of certain commercial and industrial activities pursuant to OMB Circular A-76. These studies are being conducted in the areas of dietary, housekeeping, construction trades, medical services, pharmacy, and laboratory services. They are being conducted to determine what the most efficient internal organization should be to insure maximum efficiency in the delivery of these services as well as to prepare for a determination as to whether it is more cost effective to deliver the service using in-house staff or to contract the service from the private sector. The studies were started prior to enactment of the transfer legislation and pursuant to Section 4(e) (2) of Public Law 98-621, will be among the last A-76 type studies undertaken prior to transfer.

- Reorganization initiatives are being considered at both the Hospital-wide and division levels. Reorganization planning is directed at accomplishing necessary consolidation of clinical programs (e.g. consolidation of the Godding and Noyes adult psychiatric divisions), reorganization of existing clinical divisions to increase the efficiency of service delivery (e.g. Community Mental Health Center), and reorganization at the Hospital-wide level designed to strengthen overall administration of clinical programs.

- Improvements in the area of cost accounting include review and updating of overhead allocation formulas, personnel expense allocation (allocation of individual staff costs to multiple cost centers), and review and realignment of allocations of direct cost to program activities through cost centers.

- With completion of development of an automated billing and accounts receivable management system, the focus is shifting to production of detailed management reports

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necessary to better perform revenue forecasting and improve accounts receivable management practices.

- As part of development of its five year ADP strategic plan, the Hospital is focusing on better integration of data, in order to improve analyses of the relationship beteeen patient load, service delivery, costs, revenues, and staff utilization within the clinical programs.

- Refinements in management of the Hospital's Table of Organization and its staff utilization is permitting better monitoring capabilities of staff utilization related to both FTE control and position control within the program entities.

INDEPENDENT REVENUES

Question: How much will these improvements increase independent revenues to the facility?

Answer: Improvements in accounts receivable management practices and delivery of benefits assistance services should increase the amount of revenues generated by the Hospital. In addition, many improvements described above will serve to decrease non-allowable costs, which will increase the proportion of billable costs in comparison to total cost. However, it is anticipated that improved revenue capture and cost control will be offset by a continuing trend towards a reduction of the inpatient load and its concommitant decrease in gross revenues. This trade-off between improved financial management practices and decreased patient load has resulted in maintenance of stable independent revenue estimates between FY 1984 and FY 1986.

PARTICIPATION IN D.C. PLANNING

Question: To what extent are you participating in the District's plan for a comprehensive public mental health services delivery system?

Answer: Consistent with the provisions of Public Law 98-621, DHHS and St. Elizabeths Hospital staff are participating at many levels of the District's planning effort to create a comprehensive public mental health services delivery system plan. Officials of the Public Health Service, the National Institute of Mental Health, and St. Elizabeths Hospital sit on the District's planning committee. Two prominent clinical staff have been assigned full time to the District's Mental Health Services Reorganization Office. Hospital representatives sit on the Personnel Planning Advisory Committee. Numerous clinical and administrative staff are participating in detailed planning as members of approximately 14 work groups established by the Mental Health Services Reorganization Office. Hospital and departmental staff have taken advantage of all opportunities to participate in the planning process, opportunities which have been provided by the District Government.

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CENSUS REDUCTION

Question: What community programs are being developed to assist reducing the census of the hospital?

Answer: Saint Elizabeths Hospital sponsors an on-going development of several community programs which assist us in reducing the census of the Hospital. From one (1) transitional service contract awarded to a community setting in 1977, we now have seven (7) transitional service contracts awarded to community agencies. The transitional services contractors provide socialization, employment, housing and crisis intervention for both inpatients and outpatients prior to discharge. Key staff in our Dixon Implementation Office maintain weekly contact with nursing homes and community residential facilities and provide consultation to nursing home administrators and community residential facility operators. Training programs in mental health for community operators and community agencies are developed and are offered at community sites at various time intervals throughout each fiscal year.

Three major community programs are in varying stages of development. One program involves the placement of nursing care patients who, because of behavioral and emotional problems, cannot be placed in regular nursing home settings. A second program involves the placement and follow-up of patients in community residential facilities (CRF) who are considered hard to place patients. This group of patients has not had any great degree of success in staying in CRF's. The third major program involves the training of inpatients for placement in the community who are considered at the present time to be almost impossible to place in any community setting.

Future concentration in planning to reduce the census of the Hospital will focus on joint efforts with the District of Columbia Government in the areas of residential arrangements for target groups accompanied by support services for the target groups.

CONTINUING COMMUNITY CARE

Question: Are any patients being released from the hospital without plans for continuing community care?

Answer: The Hospital always plans for delivering aftercare services. However, a number of patients do not wish to participate in such aftercare, are discharged against medical advice, and do not receive follow-up.

Question: What kind of follow-up of discharged patients does the facility conduct to ensure that needed mental health services are being provided?

Answer: Prior to discharge, Hospital clinical staff develop an outplacement plan for each patient. Any patient who consents to participating in the Hospital's outpatient treatment programs and who has not received maximum benefit of treatment is placed on convalescent leave from the Hospital and followed by the Hospital's outpatient clinics. For FY 1984, 1,811 patients were outplaced from

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inpatient care and were provided a wide range of mental health aftercare services including day hospitalization, medication, case management, psychotherapy, and allied services. During the same period, 2,499 patients were discharged from inpatient care without provision for formal outpatient services delivered by SEH. Many of these patients were directly referred to community mental health centers located in the District or other service agencies in their State of residence. Other patients were discharged against medical advice and/or chose not to take advantage of aftercare services available in the Hospital. Finally, another group of patients was referred to other residential placements, such as nursing homes, which take responsibility for providing a full range of personal services to them.

JCAH ACCREDITATION

Question: I understand that St. Elizabeths is accredited by the Joint Commission on Accreditation of Hospitals (JCAH) and certified to receive Medicare and Medicaid funds.

Are there contingencies on your JCAH accreditation, and if so, how will they be corrected?

Answer: Saint Elizabeth Hospital's Adult and Child/Adolescent Psychiatric, Alcoholism, and Forensic Programs have received a full three year accreditation as a result of a survey at the Hospital by the Joint Accreditation of Hospitals in October 1984. This accreditation is contingent upon compliance with recommendations made by the JCAH as a result of the distribution of professional staff, quality assurance activities, and therapeutic environment. The Hospital will have a focused survey concentrating on the above areas in early fall 1985. The Hospital staff has developed a plan of correction for each of the recommendations in the above areas with responsibility assigned to individual staff members for their correction. The Hospital Accreditation Committee is continuing to monitor the Hospital's progress in this area. The Hospital will have a "mock survey" in May to assess the progress being made in the quality assurance area. In addition, the Hospital has a contract with the Joint Commission on Accreditation of Hospitals to conduct a two-day workshop on Quality Assurance in June. As a result of material already submitted to the JCAH on the Hospital's Construction Program and use of Outpatient Buildings, the Joint Commission has already issued an "Equivalency" certification for most of the therapeutic environment recommendations made from the 1984 survey. This means that the JCAH feels that the plans in place at the Hospital meet the standards of the Joint Commission in this area.

Question: What is your estimate of Medicare and Medicaid reimbursements generated by residents of the facility in fiscal year 1984?

Answer: The estimate for Medicaid and Medicare reimbursements are given below. Medicaid estimates include both Federal Financial Participation (FFP) and D.C. government share. Of the amounts listed, about $1.3 million annually of Medicaid and about $1.0 million annually of Medicare represents estimated reimbursements for outpatient care.

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	Medicaid	Medicare	Total
FY 1984	$23,622	$3,290	$26,912
FY 1985	25,650	3,154	28,804
FY 1986	25,650	3,135	28,785

BUDGET REQUEST

Question: Does your budget request of $42,488,000 represent the full amount required from this Subcommittee under P.L. 98-621? (This is the legislation transferring St. E's to the D.C. government).

Answer: The budget request of $42,488,000 represents the full amount required from this Subcommittee under P.L. 98-621 for the direct Federal subsidy to St. Elizabeths Hospital to support the 1986 operating budget. This amount is consistent with the existing 10-yr plan for decreasing direct Federal responsibility for support of Hospital operations. P.L. 98-21 also authorizes the Congress to appropriate up to $25 million to D.C. to support its responsibility for the delivery of mental health services in the District. in 1986. The District must include these funds within its own budget. The funds are then requested as part of the Federal Payment to the District. This request will be considered by another Subcommittee.

D.C. SHARE OF COSTS

Question: What will be the FY 1986 District's share of funding for St. Elizabeths, and has the Mayor indicated his intention to request these funds in his budget?

Answer: The District's share of Saint Elizabeths FY 1986 budget is $62.8 million. Our discussions with the District of Columbia government have led us to believe that the District's budget is consistent with the Saint Elizabeths Hospital FY 1986 budget request.

ST. ELIZABETHS BUDGET

Question: What is the total budget for St. Elizabeths in FY 1986, including non-Federal funding sources?

Answer: The total budget for FY 1986 is $128,895,000. Of this amount $42,488,000 is the Federal subsidy, $62,781,000 is the D. C. reimbursement, and $23,626,000 represents other reimbursements.

ST. ELIZABETHS OPERATING PLAN

Question: Legislation passed last year provides for the transfer of St. Elizabeths Hospital to the D.C. government on October 1, 1987, with gradually declining Federal financial assistance through fiscal year 1991.

What is the status of the plan for transferring the management of St. Elizabeths to the D.C. government and the development of a comprehensive mental health services system for D.C. residents?

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Answer: The District of Columbia government has vigorously begun development of a preliminary plan for a comprehensive mental health services system in the District of Columbia. The Mayor has created a Mental Health Services Reorganization Office in the D.C. Department of Human Services to support this task. In addition, a planning committee, composed of District of Columbia, Federal, and private representatives has also been convened to make recommendations regarding this preliminary plan. The planning process is now well underway, with work groups established in most subject matter areas and preliminary recommendations being developed in draft. The preliminary plan is due for submission to the Mayor in October and, after review by the City Council the preliminary plan is to be submitted to Congress in January 1986. All planning activities are currently on schedule. In addition, the Hospital is preparing for full financial and physical plant audits which will be conducted in 1985. The results of these audits will be available by January 1986, consistent with the requirements of the transfer legislation.

Question: Are these transfer preparations proceeding on schedule, and do you anticipate any obstacles to accomplishing the transfer on October 1, 1987?

Answer: All of the transfer planning activities described above are proceeding on schedule. We do not anticipate any obstacles to accomplishing the transfer on October 1, 1987.

ALCOHOL RESEARCH

Question. This Committee, in its FY 1985 Report, directed NIAAA to devote a significant portion of its treatment research budget to studying the relative cost-effectiveness of varying methods of treatment as applied to patients with differing characteristics.

What types of alcoholism and alcohol abuse research are being funded now, and planned for FY 1986 to carry out this directive?

Answer. The NIAAA is currently supporting, through investigator-initiated grants, studies to assess the efficacy of several treatment modalities, including therapies conducted in hospitals, in residential treatment facilities and in outpatient programs.

In one study, the differential effectiveness of three outpatient treatment interventions is being assessed. The three modalities being tested are 1) intervention which focuses on the individual, using a social learning theory approach; 2) intervention which incorporates other significant persons, such as family members into the treatment program; and 3) intervention which adds a vocational component to the treatment program. The research is conducted through random assignment of patients to one of the three treatment modalities, and treatment of one-year duration followed by a six-month followup period.

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In another study, a broad-spectrum behavioral therapy program, involving such strategies as biofeedback is being evaluated. The Institute has also supported research to assess the effectiveness of different types of detoxification programs and research to assess the efficacy of pharmacological agents used in alcoholism treatment, such as lithium and disulfiram.

A demonstration, jointly supported with the Health Care Financing Administration, is assessing the effectiveness of lower cost alternatives for alcoholism care in Medicare and Medicaid programs. This demonstration will receive its final support this year. However the evaluation component of the project will continue in FY 1986.

Other studies, relating to the cost effectiveness of alcoholism treatment, have also been supported. These include a study of the impact of alcohol treatment services on overall health care utilization and cost for individuals and families under a Federal Employees Health Benefit Program; a demonstration with Blue Cross/Blue Shield Association to test the feasibility of broad-based coverage for alcoholism; and a study of the experience of California State employees in providing health insurance coverage for alcoholism.

These are examples of the types of research being supported by the NIAAA. Support of additional projects to systematically test the efficacy of alcoholism treatment modalities will be a high priority for FY 1986. To stimulate the research community in this regard, a special grant announcement will be issued this spring. We expect that this will result in additional meritorious proposals which can be funded in FY 1986.

Question. What kinds of treatment alternatives will be studied in this research?

Answer. The NIAAA is requesting research proposals to examine the efficacy of therapies now used in the treatment of alcoholism. These include various forms of psychotherapy; pharmacotherapy; controlled environment approaches; behavioral and cognitive restructuring therapies; family and group therapies; and educational approaches. The impact of the treatment setting is also a factor and studies which examine inpatient hospital, outpatient, residential, and auxiliary aftercare treatment alternatives will be encouraged. The type of treatment personnel is another important treatment element and studies which compare the relative effectiveness of treatment conducted by physician and nonphysician treatment personnel will also be encouraged.

BLOCK GRANT TECHNICAL ASSISTANCE

Question: What technical assistance will ADAMHA be providing to States regarding administration of the block grant pursuant to the requirements of the 1984 amendments?

Answer: In response to requests from both the National Association of State Alcohol and Drug Abuse Directors (NASADAD)

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and the National Association of State Mental Health Program Directors (NASMHPD), ADAMHA held a block grant technical assistance workshop in March, 1985, which discussed the technical assistance requirements of the new legislation and technical assistance the agency currently provides, attempted to identify areas where States felt technical assistance was needed or technical assistance currently available could be improved or expanded, and finally, developed recommendations for the continued provision of technical assistance. It is ADAMHA's intention to work closely with State representatives in implementing the recommendation of the workshop while at the same time giving the States the primary responsibility for interpreting the legislation and administering their programs.

STATE PLANNING GRANTS

Question: Congress appropriated $2.5 million for mental health state planning grants in FY 1985. Although only 10 States will have received funding--and those for only one year--you are proposing to eliminate funding for these grants in FY 1986.

What rationale is there for terminating this program after only one year?

Answer: We believe that State planning requirements are adequately provided for in each State's block grant appropriation. These particular planning grants are viewed as a one-year initiative for a few States that are in a position to benefit from this type of support.

Question: Do you think that one year is sufficient time for States to develop these plans? Would two or three years be a more appropriate time frame?

Answer: The States are expected to complete their plans this year, so that additional funding for the original group of States will not be necessary.

Question: How many applications do you anticipate receiving for these grants and of those approved, how many will you be able to fund within your $2.5 million appropriation?

Answer: The announcement for this program was mailed to the Governors of each State, Trust, and Territory in January 1985. It is difficult to predict the full extent of the response, but over 30 application kits have been mailed to the States expressing an interest in applying for funds. We expect to support a total of 10 grants with the $2.5 million appropriation.

Question: What reason do you have to believe that the "results of these efforts will be shared throughout the Nation", as stated in your budget justification?

Answer: In the announcement for the new State Comprehensive Mental Health Planning grants, States are encouraged to document and analyze the approaches they use to develop the plan and the strategy

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to implement the plan. These approaches then have to be described in a report to NIMH within 90 days following the end of the project period. The final reports on all planning grant projects will be reviewed and analyzed and a summary report will be developed which will be distributed to all of the States.

Question: Is there any indication that States are planning to use their block grant funds for developing these plans?

Answer: We have no specific information at this time as to how many States will use their block grant funds to support this planning activity. This year is the first year in which the States are specifically permitted to do so.

NIMH RESEARCH TRAINING

Question: One of the findings of the IOM study is that "NIMH now supports fewer research trainees than at any time since 1963--despite clear needs for researchers in a number of areas within the biobehavioral sciences, including for example, fields relevant to the childhood disorders."

Are you not worried that if this trend continues the field could find itself without an adequate source of talented scientists in years to come?

Answer: The NIMH 1986 budget request will support a total of 851 trainees, which is the same number as projected for the current year. We believe that our present level of support will provide enough researchers in future years and that we can, at this level, direct the program to focus on fields where there is a special need.

Question: Why does your FY 1986 budget propose to support the same number of trainees as in fiscal year 1985 in the face of this clear shortage of able young investigators?

Answer: We do not believe that there is a clear shortage of able young investigators. The production of researchers at the doctoral level remains high, and there is keen competition for our research grants.

ALCOHOL AND DRUG ABUSE DEMONSTRATIONS

Question: The 1984 Amendments authorized grants for demonstration projects relating to the prevention of alcohol and drug abuse, and for the treatment and rehabilitation of individuals suffering from these problems. Do you plan to fund any demonstrations in response to this new authority?

Answer: As you know, the ADAMHA Institutes now focus on research, with service programs to be supported by the block grant program through the States. We do not anticipate funding these service demonstrations in the future.

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ADDICTION RESEARCH CENTER

Question: Dr. Pollin, I understand that the Drug Abuse Institute supports a 32-bed inpatient facility to conduct research on addictive drugs. Can you tell me what you are doing in the area of research on drugs for the treatment of drug abuse?

Answer: The Addiction Research Center (ARC) program, in its broadest sense, is aimed at developing new methods for the treatment and prevention of drug dependence. Many of the pharmacological and psychological treatment approaches now in use -- narcotic antagonists, long acting opiod agonists, and conditioning models -- were derived directly from research done at the ARC. In addition, ARC researchers have provided objective evaluations of agents developed elsewhere which were claimed to be significant advances in the treatment of drug abuse, e.g. clonidine. Most recently, the ARC has been conducting research on buprenorphine, an agonist-antagonist agent that may have significant advantages in the treatment of opiod dependence. This work is carried out directly within the ARC, as well as in collaboration with colleagues at other academically based programs. Since the ARC does not operate its own treatment program, it is not currently involved in the design or evaluation of treatment. The new physical plant of the ARC allows for the possibility of establishing a treatment unit that could be a base for innovative approaches.

Question: Also, what is being done to assess the potential that certain substances have to be abused, since this is a stated priority of the Research Center?

Answer: The ARC has a long history of being the world's outstanding clinical laboratory for testing the abuse potential of a variety of drugs in man, including analgesics, stimulants, and hallucinogenics. It retains the capacity to carry out such studies. Over the past year about 20 to 30 percent of the clinical effort has been devoted to assessments of abuse liability of newly developed analgesic compounds. Since commercial, as well as academically based laboratories, are noew developing the capacity for such studies, the ARC facilities are gradually being reserved for the testing of new agents with special theoretical or public health interest. At the preclinical levels, the ARC works on the development of methods and techniques for evaluating drugs, but does not routinely test new compounds.

Question: Do you plan to expand the types of research being conducted at the facility in FY 1986?

Answer: No, the FY 1986 budget is essentially a current services budget and will allow the ARC to operate at essentially the same level of operations as FY 1985.

Question: Does your FY 1986 research budget request include funds to expand this facility to 32 beds, as the budget justification suggests?

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Answer: While the new building has the physical capacity to house the 32 bed ward, the operating funds provided in the FY 1986 budget will allow the use of only 10 beds. The FY 1986 budget is essentially a current services budget and will allow the ARC to operate at the same level as in FY 1985, when only 10 beds were in use.

INSTITUTE OF MEDICINE (IOM) RECOMMENDATIONS FOR ALCOHOL RESEARCH

Question. Dr. Niven, the recently released IOM Report indicates that there are many exciting opportunities for alcohol research, including research on neurobiological processes and effects of alcohol on the brain.

What are you doing in these areas, and will your FY 1986 budget request for research allow you to focus additional attention to these types of research?

Answer. Current research in the areas of neurobiological processes and effects of alcohol on the brain includes studies, at the cellular level, of alcohol's actions on the central nervous system. For example, the electrophysiological correlates of tolerance are examined by recording the firing of a single neuron. Other research at the cellular level is examining the effects of acute and long-term alcohol consumption on brain cell membranes, in relation to the structural, biochemical and functional alterations associated with alcohol tolerance and dependence. Specifically, alcohol-induced changes in the physical properties of biomembranes, lipid composition, receptor binding patterns and calcium and sodium transport are investigated.

Other ongoing research is exploring alcohol's effects on metabolism, synthesis, release and receptor interactions of neurotransmitters. The role of neuroregulators such as neuropeptides, neuroamines, endorphins and neuroamine-derived alkaloids in alcohol intoxication is also being explored.

Recent data have demonstrated that alcohol-induced brain atrophy may be reversible in abstinent alcoholics. Investigators are now monitoring and evaluating the anatomical and morphological changes by computer assisted tomography. Factors, such as duration of drinking, quantity consumed, and age, that might influence reversibility of brain atrophy are being studied.

Research into the neurobiological aspects of alcohol abuse and alcoholism will continue in FY 1986, and it is anticipated that several new projects will be funded. One area to receive special attention is the use of brain imaging techniques to study alcohol intoxication and withdrawal and alcohol's effects on glucose, oxygen and neurotransmitter metabolism in the brain. The techniques, such as CAT scan and PET scan, are non-invasive techniques for visualizing the effects of alcohol on various organs in the body. Research will also be encouraged to explore the hypothesis that alcohol impairs CNS functions by disrupting specific

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chemical processes essential for neurotransmission at critical brain sites.

IOM STUDY

Question. The IOM finds that "ADAMHA has done relatively little to help acquire the instrumentation needed to keep abreast of the field." What steps have been taken and what plans do you have to increase the agency's investment in research equipment and in facilities for investigators?

Answer. ADAMHA is pursuing a number of strategies for addressing instrumentation needs. Recently we proposed and obtained NIH's agreement to amend the guidelines for the Shared Instrumentation Grant (SIG) program in order to permit ADAMHA grantees to apply for these awards. SIG grants provide funds for equipment costing over $100,000 which will be used by at least 3 investigators with research grant support from NIH and now ADAMHA. In addition, an extramural staff policy group in ADAMHA is examining the issue of equipment funding needs. This will be done in coordination with NIH, and will include examination of mechanisms for funding, as well as assessments of need for research equipment in the biological and medical sciences.

ADAMHA Institutes also have been encouraging investigators in these fields to make use of very expensive, highly sophisticated equipment, such as PET scanners and nuclear magnetic resonance equipment, in institutions where the equipment is already available. This has resulted, e.g., in the recent finding of several projects using existing PET scanners to study mental illness.

ALCOHOLISM AND DRUG ABUSE CLINICAL TRAINING

Question: The 1984 amendments mandate that the Secretary shall make grants for the training of health professional and social work students in the identification and treatment of alcohol and drug abuse problems. How will ADAMHA be responding to this directive, and are funds requested in you FY 1986 budget to carry out this initiative?

Answer: The authorization for this program was enacted after the appropriations committees had completed their action on our bill last year. Therefore, Congress did not provide funding for this new program, but instead appropriated $22 million for clinical training in mental health with some very clear indications as to how the money should be spent. We are not, however, proposing the continuation of any clinical training programs in 1986.

It is our intention to respond to this directive by providing funds to a national organization to examine the curricula in medical education, nursing education, and other related disciplines with a view toward funding ways to promote awareness of drug abuse and alcoholism in medical students. We hope in this way to be able to use a small amount of funds in a one-year effort in such a way as to provide benefits to the alcohol and drug abuse communities over a number of years.

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CLINICAL TRAINING PAYBACK

Question: Last year, the Committee directed NIMH to develop an adequate system for monitoring and enforcing the statutory clinical training stipend payback provisions.

How is the effort proceeding?

Answer: NIMH awarded a contract to a local firm to act as agents for the government in monitoring compliance with the obligated service payback provisions. Initially, there were delays due to logistics problems and staff turnover. However, on March 25, the contractor advised us that with certain adjustments to his original schedule, he expects to have the necessary work done within the originally contemplated twelve month performance period.

Question: Has the contractor been able to identify who has received these funds since 1981 when the payback policy was implemented?

Answer: The contractor has already identified the recipients of funds, and is now printing and mailing the necessary forms for the recipients to complete.

Question: Has the contractor submitted any reports to date indicating whether and how the trainees are meeting their payback obligations?

Answer: We will be able to provide a status report indicating whether and how trainees are meeting their payback obligations after May 15, 1985 for fiscal year 1981 trainees, and June 30, 1985 for those trained in fiscal year 1982. Payback data for fiscal years 1983 and 1984 will be available after completion of the contract period. The data will actually be compiled by NIMH based on information supplied by the contractor. The contractor has responsibility for printing and mailing "Annual Clinical Training Payback Activities Certification" (APAC) forms to all trainees who have a payback obligation, and for ensuring that forms are completed and returned. The contractor missed the original target mailing date for a variety of reasons, and we have negotiated revised schedules for this phase of the work.

BLOCK GRANT DATA COLLECTION

Question. The 1984 Amendments require the Secretary in consultation with appropriate national organizations, to develop model criteria and forms for the collection of data with respect to services provided under the block grant, thus enabling States to share unform data regarding those services.

What action have you taken to implement those requirements, and what organizations have been consulted?

Answer. NIAAA and NIDA have developed and defined criteria and formats for acquiring secondary State data on clients, services, and resources in cooperation with the National Association of State Alcohol and Drug Abuse Directors (NASADAD). The efforts with NASADAD were initiated, in part, as a result of the Alcohol and

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Drug Abuse Amendments of 1983 which directed the Secretary to "work with appropriate national organizations to ensure compatible means of collecting data." With respect to mental health data, collaborative efforts among the States, the National Association of State Mental Health Program Directors (NASMHPD), and NIMH are ongoing. Model criteria and data elements were initiated in 1976 through the Mental Health Statistics Improvement Program. This collaborative effort has resulted in a single form (Inventory of Mental Health Organizations) for the collection of service, caseload, staffing, and financial data for all mental health organizations except general hospitals. These data are being collected by NIMH on a voluntary, collaborative basis, with the States providing either total or partial data on State operated and funded organizations. Current plans call for the integration of general hospitals into this system during 1986. NIMH patient surveys will also be conducted in this manner in the future.

In March 1985, the agency sponsored a block grant technical assistance workshop to discuss and exchange ideas about block grant related issues. During that workshop, ADAMHA staff discussed proposed formats and revisions to existing formats for collection data required by P.L. 98-509. The individuals consulted at the workshop included 7 State alcohol, drug abuse, and mental health directors and NASADAD and NASMHPD staff. Agency staff will also be soliciting input on the data collection activity from the National Alliance for the Mentally Ill, Mental Health Association, National Council of Community Mental Health Centers, and the Alcohol and Drug Problems Association of North America.

Question. What type of information will be collected?

Answer. Information will be collected on the types of alcohol, drug abuse, and mental health treatment and prevention programs and services conducted under the block grant, as well as those supported by other funds available to the States, and data on clients, caseload, staffing, and funding sources. These data, supplemented by information available through block grant applications, annual reports, and compliance reviews and national incidence and prevalence studies sponsored by the ADAMHA Institutes should provide sufficient data to meet the intent of the legislation.

BLOCK GRANT DATA DISSEMINATION

Question. What plans do you have for disseminating the information obtained to service providers?

Answer. The agency plans to disseminate the block grant information it collects to the State alcohol, drug abuse, and mental health directors. The State directors may choose to disseminate the information to service providers in their States. At the present time, ADAMHA does not have specific plans to distribute the block grant information we collect directly to service providers, although this information will be available through established agency mechanisms such as national meetings and conferences, The National Clearinghouse for Alcohol Information, National Clearinghouse on Drug Abuse Information, National Technical Information Service, and agency publications including

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ADAMHA News, NIDA's Clinical Research Notes, Mental Health Services System Reports, and Alcohol Health and Research World.

COMMUNITY SUPPORT SERVICES FOR CHILDREN

Question: The Child and Adolescent Services program, initiated at the direction of Congress, is targeted towards improving services to seriously emotionally disturbed children.

Between 20 and 25 States are currently being funded through five-year grants, but will be terminated before their completion if your proposal to eliminate CSP is agreed to.

Why do you believe there is no longer a need for Federal involvement in meeting the needs of our children who are seriously mentally ill?

Answer: We believe that the Federal involvement should focus on research, not the direct provisions of services. The Child and Adolescent Service Systems Program (CASSP) was started in 1984 and is accomplishing some of its purposes. With funds appropriated in 1984, NIMH initiated CASSP with activities in two major areas: State grants and technical assistance and resource development. The technical assistance program was developed to transfer knowledge on the latest information concerning child mental health services and system development to both funded and unfunded States. Therefore, we have built in some assurance that the results of the past two years will be widely disseminated. The 20 States that will have been funded through 1985 can serve as examples for other States with respect to initial planning for State-level system development.

CHILD RESEARCH AND TRAINING CENTERS

Question: Who can States look to for technical assistance on childrens' mental health programs, if your two research and training centers are eliminated?

Answer: The two Research and Training Centers are funded jointly by the National Institute of Mental Health (NIMH) and the National Institute of Handicapped Research (NIHR) through a Department of Education grant. If NIMH funding were eliminated, these centers could still receive 75% of their FY 1985 allotment from NIHR in FY 1986. In addition, technical assistance provided directly by NIMH staff would still be available to States.

NIMH RESEARCH ON THE AGED

Question: What types of research is NIMH supporting with regard to the mental health needs of the aged?

Answer: The NIMH research program on the mental health needs of the aged is a broadly based and comprehensive approach addressing (1) biomedical research on the nature, distribution, causes, and treatments of the major mental disorders, particularly the dementing disorders including Alzheimer's disease, depression, anxiety, schizophrenia, and sleep disorders; (2) behavioral and services research on these disorders including studies of family support,

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rehabilitation, services design and evaluation; and (3) risk identification and prevention-oriented studies of these disorders including studies of stress, coping, and social support. Special initiatives underway or planned include programs to support: clinical research centers on psychopathology of the elderly; research on mental illness in nursing homes; research on the interaction of mental disorders and physical illness in late life; and research on family stress and the care of Alzheimer's disease victims.

Question: Specifically, has your research on the dementias indicated any reason why those afflicted are mostly women?

Answer: For many dementing disorders with known risk factors, e.g., alcohol abuse and Korsakoff's syndrome or hypertension/stroke and multi-infarct dementia, the prevalence would be higher for men. In the most frequently occurring dementing disorder, Alzheimer's disease, the only reliably identified risk factor is advanced age, with a prevalence rate of 20% in the 80+ age group. The older age groups are disproportionately made up of women, for reasons that are not entirely clear. Therefore, because of their greater life expectancy women are at higher risk for Alzheimer's. No other more specific genetic or hormonal gender-linked asssociation has been identified to account for this difference.

COORDINATION WITH NIA

Question: To what extent are you coordinating research efforts related to Alzheimer's disease with the National Institute on Aging?

Answer: The NIMH and the National Institute on Aging (NIA) use a number of mechanisms to assure coordination of research programs. These include membership on the Interagency Committee on Research in Aging; review of each Institute's referral guidelines for the assignment of research grants; dual assignments of relevant research projects; participation in planning of conferences; and acknowledgement of joint interest in several research areas in published Requests for Applications.

Research on Alzheimer's disease uses all of these coordinating mechanisms. In addition, the Director of NIMH and the Director of NIA will serve on the Secretary's Task Force on Alzheimer's disease, the major departmental coordinating body in this area. NIMH staff also participated in the developement of the NIA program to develop Alzheimer's disease research centers and recommended panels of scientists to serve as reviewers.

In general terms, the NIA approach and the NIMH approach are complementary with NIA emphasizing basic science and the search for cause while the NIMH approach focuses on clinical and services issues.

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CLINICAL TRAINING PHASE-OUT

Question: I see you are once again proposing to eliminate funding for the clinical training of mental health professionals, for which Congress provided $22 million last year.

What information do you have to indicate that shortages in areas targeted by Congress as deserving of special attention, such as geriatric and mental health care, no longer exist?

Answer: Some shortages in these areas may still exist, but we believe that the educational system has the capacity to train people to fill them without additional Federal help. We have now trained a number of geriatric mental health specialists who are prepared to teach others in their fields and have started a number of geriatric mental health programs. These should now function on their own.

Question: What other sources of support exist in the absence of Federal support for the training of clinical personnel?

Answer: Training departments typically get their funds from tuition, interest on endowments, funds generated from services rendered, and, in the case of State universities, State money. Students may have part-time jobs, either in the university or outside, have help from spouses or partners, use their savings, or they may have to take out loans.

SHORTAGE OF PSYCHIATRISTS

Question: Is there still a potential shortage of psychiatrists, and if so, how will this need be met if clinical training funds are eliminated?

Answer: There is not an overall shortage of psychiatrists, although there may be shortages in certain subspecialty areas. We do not believe that Federal support is necessarily the only way to address this problem. Since there is an ample supply of mental health professionals generally, we believe that they will of their own accord choose to specialize in those areas where there are shortages and job opportunities. Federal programs in the past have built up a training capacity in these areas, so that there are programs to train interested professionals.

Question: Are we in the position now of having sufficient psychiatrists, psychiatric nurses, social workers, and psychologists in the underserved rural and inner city areas?

Answer: No, there are still some shortages in these areas. However, as the supply of mental health professionals increases, practitioners have to accept the less desirable jobs in rural and inner city areas. Overall, the training and production of mental health professionals has remained strong, and people are working in inner city and rural areas.

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NEW BLOCK GRANT SET-ASIDE

Question: The 1984 Alcohol, Drug Abuse and Mental Health Amendments required States to use at least 5 percent of their block grant allotment to initiate and provide new alcohol and drug abuse services for women. In addition, States are now required to use at least 10 percent of their mental health funds to initiate and provide new mental health services for severely disturbed children and adolescents, and new comprehensive community mental health programs for underserved areas and populations. How are you ensuring that States actually implement these new requirements?

Answer: ADAMHA has advised each State and territory that receipt of their full 1985 award amount will be contingent upon ADAMHA's receiving certification by the governor that the State will comply with requirements of the new legislation concerning the set-aside for women and new mental health services. To date we have received such certification from 48 States and territories and expect to receive it from all remaining States shortly. In addition, ADAMHA will monitor States implementation of the new set-asides through the normal compliance review process, and reviews of the 1985 audits and annual reports of each State.

Question: What types of activities are being supported with these funds?

Answer: At present our discussions with the States and Territories receiving ADMS block grant funds indicate that most of their plans for expending set-aside funds include the creation of new programs and expansion of existing services to include a larger number of participants. A detailed listing of the type of activities which are supported by these funds will be included in the annual reports covering fiscal year 1985.

RESEARCH ON ALCOHOL AND DRUG ABUSE PROBLEMS AMONG WOMEN

Question. The 1984 Amendments placed increased emphasis on alcohol and drug abuse research devoted to the problems of women.

What types of research are you currently supporting in these areas?

Answer. NIDA sponsors a wide range of research directed at women, most of which involves studies of the special hazards posed by drug use by women, and, in particular, on the effects of drug use on reproductive function. The NIAAA is currently supporting studies of physiological and biobehavioral consequences of alcohol consumption in women, including studies of the covariance between alcohol consumption patterns and phases of the menstrual cycle. These studies seek to clarify possible hormonal determinants and indicate if alcohol has direct toxic effects on the episodic secretory patterns of hormones which regulate the normal female reproduction function.

The NIAAA is also currently supporting epidemiologic research into alcohol-related problems among women. The Institute has supported a survey, involving several hundred women, which measured drinking behaviors and consequences, gathered data on a

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large number of psychological and social variables, and used a comparison sample of men to permit analysis of the similarities and differences between the sexes with respect to the antecedents and consequences of drinking. This was the first national survey of drinking problems among women and has yielded a large set of data, currently being analyzed, on the patterns, antecedents and consequences of women's alcohol problems. A followup survey of 300 women from the previous survey will begin this year.

Question. Will you be increasing the level of effort in these areas in FY 1986?

Answer. It is expected that the total support of research to investigate specific alcohol and drug abuse problems of women in 1986 will be $2.4 million. This represents an increase from 1985 of approximately 65% for NIDA and 40% for NIAAA.

Question. Do you have any new information on the reproductive disorders associated with alcohol abuse among some women?

Answer. It is now known that alcohol abuse in women is associated with several derangements in the reproductive system, including absence of menstruation, infertility, and spontaneous abortion. The mechanism of these reproductive disturbances is unknown, but there is clinical evidence that alcohol has a toxic effect on the hypothalamus and pituitary. These organs are parts of the endocrine system that control the secretion of gonadotropins, which are sex hormones that stimulate ovulation and sustain pregnancy.

Current research is attempting to determine the specific part of the endocrine system where alcohol exerts its toxic effects. Three parts of the endocrine system are being investigated: the hypothalamus, the pituitary and the ovaries. Collectively these organs are referred to as the hypothalamic-pituitary-ovarian axis, because they represent a hierarchy of endocrine functioning; that is, certain hormones secreted by the hypothalamus trigger the secretion of other hormones by the pituitary, and these in turn trigger hormone secretion by the ovaries. The hormones secreted by the ovaries are responsible for regulation of the menstrual cycle and the maintenance of pregnancy. Once the site of alcohol damage has been identified, it may be possible to find ways to reverse the reproductive system damage caused by alcohol.

DETERMINATION OF BLOCK GRANT ALLOTMENTS

Question. The 1984 amendments mandated differing formulas for allocating the block grant funds, based on the amount of the appropriation. Further, the Secretary was required to provide for a non-governmental review of the allocation process to determine whether a more equitable process can be devised than the one specified in the law.

What steps have been taken to begin a review of the block grant formula?

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Answer. Within the next several months ADAMHA expects to award a contract to carry out a detailed review of the allotment of ADMS block grant funds to States under the current and alternative ADMS legislative formulas. The study will examine in detail such factors as the financial resources of the States, their populations and various relevant conditions and circumstances that have changed since the enactment of the legislation. In addition, the study will examine the additional factor of the various States' needs for alcohol abuse, drug abuse and mental health services, and carefully assess appropriate measures for determining these needs. Throughout the study the contractor will consult with appropriate representatives of both State and local governments.

To assist in the planning and direction of this project a special ADAMHA work group has been established, which is currently developing the work specifications for the contract. We expect to have the study under way by early summer to allow ample time for a full and complete review of the issues and to facilitate timely preparation of the Secretary's report to the Congress in October 1986.

1986 CURRENT SERVICES BUDGET

Question. Please provide for the record the amounts needed in FY 1986 for each of the institutes, and the block grant, in order to continue the operations at current services level.

Answer. The requested information is provided in the following table.

	1985 Appropriation 1/	1986 Current Services
NIMH		
Research	$195,200,000	$222,712,000
Planning & Demonstrations	13,000,000	13,598,000
Research Training	18,000,000	18,828,000
Clinical Training	22,000,000	23,012,000
Direct Operations	34,426,000	36,482,000
Total	282,626,000	314,632,000
NIDA		
Research	64,320,000	70,221,000
Research Training	1,500,000	1,569,000
Direct Operations	15,310,000	16,189,000
Total	81,130,000	87,979,000
NIAAA		
Research	48,785,000	56,690,000
Research Training	1,500,000	1,569,000
Direct Operations	11,961,000	12,618,000
Total	62,246,000	70,877,000
Buildings and Facilities	---	100,000
Program Management	7,624,000	8,162,000
Block Grant	490,000,000	512,540,000
Total	$923,626,000	$994,290,000

1/ Excludes amounts to be setaside under the Treasury-Postal Services Appropriation Act, 1985.

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RESEARCH GRANT PRIORITY SCORES

Question. What do you anticipate that the priority score cut-off point will be under your FY 1986 budget proposal for research? Please provide the cut-off scores for FY 1981, 1982, 1983, 1984 and 1985 as well.

Answer. The priority score cut-off point for 90% of all regular research projects funded from 1981 through 1986 are as follows:

	Payline
1981.....	219
1982.....	206
1983.....	180
1984.....	172
1985 Appropriation	171
1985 Current Est..	168
1986 Estimate.....	162

Question. Aren't you concerned that, if this cut-off point gets too low, many highly qualified investigators will not be able to receive Federal support and will leave the field of research?

Answer. As long as the number of new and competing regular research grants remain stable at 500, we feel that the field will remain of interest to highly qualified investigators. A reduction in the payline does not necessarily equate to a more restrictive environment for investigators in the ADM field. The reduction of the cut-off point is due to several factors including a real improvement in the quality of applications being received and a shift in our research in the direction of basic biomedical or "hard" science where the scores tend to be better because the experimental projects can be more close controlled. While some investigators may in fact leave the research field or switch to research in some other area, a stabilized research funding base should ensure that many highly-qualified investigators remain committed to ADM studies.

FY 1985 RESCISSION REQUEST

Question: Please provide a breakout, by Institute and category (i.e., travel, consultants, etc.), of your FY 1985 rescission request. Also indicate any initiatives that will be foregone and/or postponed until FY 1986.

Answer: The 1985 rescissions required under Section 2901 of the Deficit Reduction Act are as follows:

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Total Rescission by Activity

(Dollars in thousands)

	Travel	Public Affairs	Publishing	Consulting Services	Total
NIMH:					
Other Research Mechanisms...	$---	$---	$---	-$357	-$357
Direct Opers..	-233	-107	-699	-357	-1,396
Subtotal..	-233	-107	-699	-714	-1,753
NIDA:					
Other Research Mechanisms...	---	---	---	-231	-231
Direct Opers..	-45	-15	-477	-69	-606
Subtotal..	-45	-15	-477	-300	-837
NIAAA:					
Other Research Mechanisms...	---	---	---	-447	-447
Direct Opers..	-52	-40	-389	-274	-755
Subtotal...	-52	-40	-389	-721	-1,202
Program Management....	-8	-75	-60	-37	-180
Total.....	-$338	-$237	-$1,625	-$1,772	-$3,972

Several initiatives will either be reduced in scope in 1985 or postponed until 1986, including drug and alcohol abuse prevention media campaigns and a stigma campaign aimed at educating the public of mental health developments and reducing the stigma of mental illness.

RESEARCH GRANT PAYLINES

Question. Please provide for the record what your 90% payline was for fiscal years 1975-1984.

Answer. The chart below shows our 90% payline for 1975-1984.

90% Payline of Funded Projects	Payline
1975	280
1976	281
1977	265
1978	254
1979	250
1980	257
1981	219
1982	206
1983	180
1984	172

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Question. If you were to make 83 additional new research grant awards in FY 1986, what would your paylines be?

Answer. Our 90% payline for 1986 would be 168 if 583 awards were made.

NIAAA CLINICAL UNIT

Question. Dr. Niven, can you describe for us what kinds of research are being conducted at your 10-bed unit at NIH?

Answer. Since the clinical ward opened in January, 1984, a very active research program has been developed which allows us to look at the problems associated with the development and treatment of alcohol and alcohol-induced organ pathologies from a number of different perspectives and levels of investigation. Research studies now in progress include, for example, investigations on the development of dependence and tolerance; the alcohol withdrawal syndrome and the development of improved treatment strategies; cognitive and psychomotor impairments associated with acute and chronic use of alcohol; pharmacologic treatments to improve behavioral function in patients with chronic alcohol-induced brain disease; genetics, at the DNA and protein levels, of alcoholism and of specific alcohol-induced disease states; the role of family in the transmission or prevention of alcoholism; and the relationship of alcohol use to neuroendocrine and cardiovascular functioning and disorders. Following are specific examples of the range of studies now being conducted in our clinical program.

Studies by intramural researchers are addressing the clinically important question of the interactions between alcohol and nutrition in the development of alcoholism and particularly the associated organic brain damage exemplified by the Wernicke-Korsakoff syndrome. Chronic, organic brain syndromes associated with alcoholism, such as Korsakoff's psychosis and alcohol-induced dementias, are the second most common cause of dementia (after Alzheimer's disease) in adults. It is well-established that a major causative factor in the development of the Wernicke-Korsakoff syndrome is the thiamine (vitamin B) deficiency that accompanies alcohol abuse due to inadequate nutritional intake, decreased absorption, or impaired utilization.

Current research is addressing the genetic predisposition to development of thiamine deficiency, its contribution to alcoholism-associated dysfunction of brain and other organ systems, and its possibly causative role in the development of alcoholism. Studies thus far have investigated the function of a thiamine-dependent enzyme (transketolase) and have found differences in its activity between Korsakoff patients, alcoholics, and non-alcoholics. These findings and those from father-son studies, suggest that a putative inborn error of predisposition to thiamine deficiency diseases, similar to that in Korsakoff psychosis, may be more prevalent in male familial alcoholics as well as in their male offspring even

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before exposure to alcohol. If confirmed by current investigations, this work would predict that if the sons of the alcoholics start abusing alcohol, they would be at higher risk for brain damage as compared to the offspring of the general population at large. Studies looking at family members of Korsakoff patients and at individuals with different transketolase phenotypes will help to address these issues.

At a different level of analysis, researchers are studying the role of neurotransmitters in the development of alcoholism, intoxication, and withdrawal and their possible usefulness as therapeutic agents. Neurotransmitters, and particularly the biogenic amines, have been postulated to play a major role in regulating reward and punishment responses, mood, and aggression, and in other studies a less well-defined role in the development of alcoholism, ethanol intoxication and withdrawal, and the development of tolerance to ethanol.

Intramural scientists have taken the lead in the development of assays for directly and thus more precisely measuring specific monoamines in various tissues and body fluids. This will provide an important research and clinical tool and is a major technical advance. In related neurotransmitter studies, researchers are using the most transmitter-specific drugs clinically available to modify the effects of alcohol on performance in humans. For example, investigators have found that zimelidine (a serotonin reuptake inhibitor) can reverse certain adverse effects of alcohol on memory. Scientists are also currently involved in studies using transmitter precursors to reduce the relapse rate of alcoholics to drinking, and are developing the capability to quantify various neuroreceptor functions in these patients. These studies will provide the foundation for important pharmacological advances in preventing and treating the harmful behavioral and neuropharmacologic effects of alcohol abuse.

Other investigations on the clinical ward are seeking to delineate the neuropsychological characteristics of two understudied patient populations, each of which is critical to understanding the natural history of alcoholism. The first involves young men and women who have had an alcohol problem for a relatively short period of time. This group is of particular interest because it is unknown whether cognitive impairment is present in such alcoholics. The second patient group consists of alcoholics with clinically defined organic brain syndromes.

These studies will help to determine whether continued alcohol abuse predictably results in specific chronic organic brain syndromes, the effects of abstinence on subsequent cognitive functioning, and the effects of different consumption patterns in early alcohol dependency on neuropsychological functioning. These results will provide important clinical information for physicians and other health care professionals when developing treatment strategies matched to the needs of their patients.

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INDIRECT COSTS

Question. Is it true that your anticipated indirect cost rate will be 45% in FY 1986? If so, what accounts for this high rate?

Answer. You are correct that our anticipated indirect cost rate for our project grant program will be 45% for 1986. This amounts to approximately 31% of the total dollars for each award which is comparable to the indirect costs paid by all health agencies but a lower percentage than that typically paid on contracts. The indirect cost rates for institutions are negotiated individually and all costs are periodically audited. As a result, we believe the indirect costs for which this agency pays are both legitimate and integral to the conduct of research. As to the 45% rate, we, as well as others, are concerned with the increases in the average rate over the last few years. This concern has become of such a magnitude that the entire indirect cost issue has been referred to the Office of Science and Technology Policy for their review on a government-wide basis.

Question. What kinds of expenses are covered as indirect costs?

Answer. Indirect costs for research at a college or university usually include expenses for:

--- sponsored project administration,
--- general administration,
--- departmental administration,
--- operation and maintenance,
--- student services,
--- library costs, and
--- use charges for building and equipment.

Questions Submitted by Senator William Proxmire

ALCOHOLISM TREATMENT ASSESSMENT RESEARCH

Question. Last year we discussed your plans to cooperate with the Department of Defense on alcoholism treatment outcome research. You stated that the first phase of that research would be a study to define what the benefits and costs would be, and what would be the best way to proceed.

Can you tell us where you stand on this project?

Answer. We have examined the relative benefits and costs of conducting a major controlled clinical trials study utilizing military personnel undergoing alcoholism treatment. We have concluded that while such a study could add important knowledge on treatment outcome among this population group, the military population should be seen as only one of many populations we wish to study in the most cost-efficient manner possible. Thus we do not plan to initiate a major contract for a study on alcoholism treatment outcome in military settings.

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although grant proposals for such research would be considered along with proposals addressing other populations.

The Institute has concluded that the best way to proceed with treatment efficacy research is through the investigator-initiated grant mechanism. Toward this end, the Institute issued a general grant program announcement in the spring of 1984 and plans to release a second, highly focused treatment research grant announcement this spring. It is anticipated that these two announcements will result in meritorious treatment research proposals addressing a variety of treatment populations and treatment methods.

PREVENTION RESEARCH SUPPORT

Question: Dr. Frazier, back in 1973 you obligated $7,910,000 for extramural research into preventing mental illness. Your 1985 budget justifications indicated that you planned to spend $10,100,000 on this activity in 1984 and $10,200,000 in 1985. It now appears that you have decided to cut your projected prevention research activities in half. Your 1986 justifications indicate you spent only $4,690,000 in 1984 and plan to spend just $5,345,000 in 1985.

Why did you decide to make this dramatic about face?

Answer: The discrepancies you note are essentially the result of a technical adjustment; we have in fact maintained the same level of effort as originally planned for both years. The variance in estimates results from a change in the method of reporting obligations by area of research.

Individual grants frequently relate to two or more of the priority areas used in our justifications. However, the official accounting system which reports by mechanism, organization and type of award cannot sort out the varying degrees of effort which each grant may allocate to our ten research priority areas. For example, grants funded by our Center for Prevention have significant components relating to other priorities such as studies of the brain, depression, or schizophrenia. For this reason we have, for several years, sought a reporting system which reasonably portrays our program efforts while maintaining the integrity of our regular accounting system.

The previous method used in 1985 and in earlier budgets employed a two-step process. First, our ten research priorities were arranged in the following hierarchical order: (1) basic studies in brain and behavior; (2) schizophrenia; (3) depression and manic depressive illness; (4) aging; (5) childhood disorders; (6) anxiety; (7) stress and psychosomatic disorders; (8) epidemiology; (9) prevention; and (10) other mental health areas. Second, this sequence was applied to each grant, and the entire dollar value of the grant was attributed to the first subject area covered by any component of that project. In the case of prevention and epidemiology, a third step was employed. Because the Institute has organizational units identified specifically with these priorities--a Division of Biometry and a Center for Prevention--the obligations reported for these programs were adjusted to reflect not

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less than the amounts allocated to them through the official accounting system. Approximately one year ago, after the 1985 budget was submitted, the reporting system was changed. The 1986 budget reflects a distribution which allocates the cost of a single grant to as many as three priority areas, provided that at least 30 percent of the value of the grant pertains to the given area. In addition, we no longer require that funds allocated for prevention or epidemiology equal the organizational allocation. We find the current method to be a more accurate portrayal of our expenditures.

Question: Last year's justification indicated you planned to fund 1,616 total compensable work years in 1985. This year's justifications show an adjusted figure of 1,592 total compensable work years in 1985. Can you explain this reduction?

Answer: This reduction is consistent with our efforts to achieve an FTE usage level which is less than we proposed last year, or 1,527 FTEs for those workhours charged against ceiling.

INCREASE IN AVERAGE GRADE

Question. Last year you estimated your average GS grade would be 10.50 in fiscal year 1985, a slight reduction in your 1984 average. Your current estimate is that the average grade will actually creep up to 10.76 in 1985.

Why weren't you successful in scaling back your grade structure?

Answer. As discussed earlier, the agency is currently under a hiring freeze anticipated to be in place for all of fiscal year 1985. The purpose of this freeze is to bring the agency down to our proposed FTE target of 1,512. We anticipate hiring very few staff this year, and the expected attrition which will reduce our FTE utilization will result in more lower graded than higher graded staff leaving the agency. There is greater mobility within the lower grades and as a result these are the majority of positions vacated. Thus, attrition will create the slight average grade increase you note.

SAINT ELIZABETHS HOSPITAL SUPPLIES

Question: Dr. Frazier, last year's justifications for St. Elizabeths Hospital indicated you planned to spend $10,874,000 for supplies and materials in 1985. Your current estimate for supplies and materials is $9,121,000.

How will that saving of approximately $1.7 million be achieved?

Answer: The Hospital has to absorb $2.6 million for the FY 1985 pay raise. This absorption of funds will be accomplished by saving $800,000 in the personnel budget while the rest must be realized through other savings, e.g. $1.7 million will be saved in supplies and materials by cutting back on other than critical items. The Hospital started this fiscal year with full fuel oil tanks and a well-stocked warehouse which will help the Hospital absorb this added payroll cost of $2.6 million.

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Questions Submitted by Senator Daniel K. Inouye

SUPPLY OF MENTAL HEALTH PRACTITIONERS

Question: Universities are beginning to experience decreased enrollments in psychiatric mental health nursing programs. This is at a time when there is increased demand in this country for these nurse specialists to care for persons with mental disorders. Testimony indicated that 19 percent of the nation's population suffered from a diagnosable psychiatric disorder. Projections of the future prevalence of mental illness indicate that if the number of psychiatric nurses does not increase, the country will experience a major nursing shortage.

What is the Administration's request for mental health clinical training and how will this affect the supply of core mental health practitioners?

Answer: The Administration is requesting no funds for clinical training in FY 1986. We believe that the training institutions have the capacity to produce sufficient numbers of mental health personnel without Federal assistance, and that elimination of the small Federal effort will have little impact on the supply of mental health practitioners. Sometimes students will attend school part-time and work part-time, as often happens with psychiatric nurses. This appears to be the reason for the drop in full-time students. The overall supply of mental health professionals, including psychiatric nurses, seems sufficient to meet the demand, as shown by the job market.

SAINT ELIZABETHS HOSPITAL STAFFING

Question: What is your budget request for full-time equivalent staff and how does this compare with fiscal year 1985?

Answer: We are requesting a total of 3,458 full-time equivalents in 1986, and this number is the same as for 1985. Within that total, the number supported by direct Federal appropriations will decline from 1,335 in 1985 to 1,092 in 1986.

Question: A recent report in Capitol Nursing indicated that the starting salaries for nurses in the Federal government were the lowest in the Washington Metropolitan area. What is the anticipated impact of the 5 percent pay cut on the recruitment and retention of clinical personnel?

Answer: The Hospital has not formally evaluated the potential impact of a 5 percent pay cut on the recruitment and retention of registered nurses. We do know, however, that we are currently experiencing difficulty in recruiting and retaining the number of nurses that are needed. For our part, we will continue to offer incentives to encourage employment affiliation with the Hospital: a nursing internship program, a Marymount College Satellite campus on the grounds to facilitate continuing of formalized education; support for full time training for up to one year through competitive selection procedures, flexible scheduling, etc.

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OFFICE FOR CIVIL RIGHTS

STATEMENT OF BETTY LOU DOTSON, DIRECTOR

ACCOMPANIED BY:

BART J. CRIVELLA, DEPUTY DIRECTOR FOR MANAGEMENT AND POLICY

PAUL R. KRETCHMAR, ASSOCIATE DEPUTY DIRECTOR

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY FOR BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

JOHN T. HOPKINS, DIRECTOR, DIVISION OF BUDGET SERVICES, OFFICE OF THE SECRETARY

PREPARED STATEMENT

Senator PROXMIRE [presiding]. Our last witness this morning is Betty Lou Dotson, Director of the Office for Civil Rights who will present the fiscal year 1986 budget for that office.

Ms. Dotson, I note that your request proposes a decrease of $574,000 from the fiscal year 1985 amount.

Please proceed with a summary of your statement, and then we will go ahead with the questions.

Before you start, we will insert your prepared statement into the record.

[The statement follows:]

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Statement of Betty Lou Dotson

I appreciate the opportunity to present the fiscal year 1986 budget request for the Office for Civil Rights (OCR).

OCR is requesting $19,636,000 in obligational authority, a decrease of $574,000 compared to the FY 1985 amount. Of the total budget request, $15,636,000 would be provided in budget authority, together with $4,000,000 to be transferred from the Social Security and Hospital Insurance trust funds. This compares to $17,850,000 in budget authority and a transfer of $2,350,000 in FY 1985. We propose to increase the amount of the transfer in FY 1986 to bring the amount more in line with the proportion of OCR's workload devoted to Medicare providers and other trust fund-related compliance activities.

The budget request would provide 396 full-time equivalent (FTE) staff compared to 402 FTEs in FY 1985. This smaller staff size is consistent with the Administration's overall program to decrease Federal employment, restrain spending, and reduce the Federal deficit. Under this policy, OCR will achieve dollar savings throughout FY 1985 and FY 1986 through attrition and a closely controlled hiring policy. The savings will enable OCR to absorb the cost of the FY 1985 pay raise and other cost increases in FY 1986.

We believe the cost-saving measures can be carried out without seriously affecting OCR's compliance program. It should be noted, for example, that the discrimination complaint workload has declined since FY 1981 and has stabilized at about 1,165 new complaints annually. This trend, coupled with productivity gains, has enabled OCR to shift staff resources to other equally productive compliance areas. In FY 1986, OCR expects to equal or exceed the FY 1985 program accomplishments.

Since 1981, OCR has undertaken an innovative, and more comprehensive and effective compliance approach emphasizing reviews, voluntary compliance and outreach efforts. This approach is designed to ensure that the rights of HHS beneficiaries and potential beneficiaries are protected "proactively" and not solely by the "reactive" complaint activity. The FY 1986 budget for civil rights will maintain this forward momentum.

Compliance Responsibility

The mission of the Office for Civil Rights (OCR) is to eliminate unlawful discrimination and to ensure equal opportunities for the beneficiaries and potential beneficiaries of Federal financial assistance provided by the Department of Health and Human Services. OCR's objective is to accomplish its mission as effectively and efficiently as possible, with meaningful efforts to obtain voluntary compliance.

The Office for Civil Rights enforces various civil rights laws and regulations that prohibit discrimination on a variety of bases including race, color, national origin, handicap and age. OCR also enforces the community services assurance under which health care facilities assisted by the Hill-Burton Act must provide health care

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services to all persons residing in the service area without discrimination. Finally, OCR enforces the nondiscrimination provisions enacted under the health care and other block grants administered by the Department.

Compliance Activities

In fiscal year 1986, OCR will continue a pro-active compliance program designed to generate voluntary compliance on a wide scale among the Department's federally assisted programs and services. A total of 321 FTEs will be allocated to conduct reviews, monitor corrective action plans, carry out voluntary compliance and outreach activities, and to process discrimination complaints. These are the methods by which OCR follows up on information of alleged noncompliance and seeks to eliminate or prevent discrimination.

Reviews and Monitoring

The Department is obligated by regulation to periodically review the practices of recipients to determine whether or not patterns or practices of discrimination exist in Department-funded programs. Typically, OCR makes such assessments by conducting compliance reviews. OCR also conducts project reviews to follow up on specific compliance issues that have come to our attention through analyses of survey data or other compliance information. OCR plans to conduct approximately 810 compliance and project reviews in FY 1986, the same number as in FY 1985. The year-end inventory in FY 1986 should also remain about the same.

OCR also conducts pre-grant reviews when we are notified by the Health Care Financing Administration that a health care facility has applied to participate in the Medicare program and must receive civil rights clearance. Approximately 3,500 pre-grant reviews will be completed in FY 1986.

If a review reveals or substantiates a compliance problem, OCR requires the program recipient to adopt and implement corrective measures. In addition, by means of written agreements, facilities subject to pre-grant reviews may be required to submit compliance information. Corrective action plans and agreements are monitored by OCR to assure full compliance. In recent years monitoring actions have risen sharply due to project reviews, initiated in FY 1983, and an increasing number of annual pre-grant reviews. In FY 1986 OCR will monitor approximately 1,930 plans and agreements.

Voluntary Compliance and Outreach

The goal of OCR's voluntary compliance activity is to assist recipients in complying voluntarily with the requirements of civil rights laws and regulations in the most cost-effective way. Regional voluntary compliance and outreach staff directly provide technical assistance to recipient institutions, state and local agencies.

Under our outreach effort, OCR seeks to help beneficiaries and potential beneficiaries of HHS-funded programs to understand their rights and responsibilities under applicable civil rights laws and regulations, and to stimulate their participation in voluntary compliance-related activities of recipient institutions.

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In FY 1986, OCR will continue to furnish technical assistance and compliance information to program recipients and beneficiaries through training, on-site consultations, conferences, and other contacts. Special projects will be undertaken to implement civil rights compliance procedures and outreach efforts with State and area aging agencies, the Administration on Developmental Disabilities, and the refugee resettlement program.

Complaint Investigations

Under the regulations implementing civil rights statutes, OCR is required to address discrimination complaints involving HHS programs in a timely manner. In addition, the Department of Justice, which coordinates civil rights enforcement government-wide, requires that each compliance agency such as OCR have procedures to resolve discrimination complaints promptly.

OCR expects to receive about 1,165 new complaints in fiscal year 1986, the same as the 1985 estimate. The 119 FTEs assigned to this activity will be adequate to process the complaint workload and reduce the year-end inventory.

Legal Services

OCR's budget request includes 33 FTEs to staff the Civil Rights Division of the Department's Office of the General Counsel, the same allocation that was made in fiscal year 1985.

The staff attorneys in the Civil Rights Division provide OCR with a wide range of legal advice in: (1) interpreting and applying the nondiscrimination provisions; (2) interpreting court decisions; (3) providing legal guidance in applying the Privacy Act, the Freedom of Information Act and other statutes or regulations with which OCR must comply; and (4) when appropriate, conducting enforcement proceedings and referring cases to the Department of Justice.

Program Management

In fiscal year 1986 OCR will allocate 42 FTEs to program management, a decrease of one FTE.

Management staff determine program objectives and priorities, formulate and execute the OCR budget, monitor the compliance effort and evaluate progress, and make final decisions about OCR's compliance standards and procedures.

In addition, management staff provide administrative support in such areas as personnel management; travel; procurement; and, management of ADP, property, and supply systems.

Conclusion

In conclusion, Mr. Chairman, OCR's fiscal year 1986 budget request would provide 396 FTEs and $15,636,000, together with $4,000,000 to be transferred from the Social Security and Hospital Insurance trust funds. We believe this budget will enable OCR to maintain its program priorities and conduct an effective compliance program.

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Biography of Betty Lou Dotson

Position:

Director, Office for Civil Rights
Special Assistant to the Secretary
for Civil Rights
Department of Health and Human Services

Former Positions:

Ms. Dotson began her Federal Service in 1956 with the Social Security Administration and served with the Department of Agriculture as: Director of the Civil Rights Staff, Food and Nutrition Service; Assistant to the Director of Equal Opportunity at the Department level; and most recently, Chief of the Adjudications and Complaint Division, Office of Equal Opportunity. She also served as Assistant Director for Equal Opportunity at ACTION from 1975 through 1978.

During 1979 - 1980, Ms. Dotson served at the Joint Center for Political Studies on an Intergovernmental Personnel Act assignment.

Ms. Dotson has more than 20 years of experience in the legal and social services area. Early in her career, she worked in the legal services trust department of the First National Bank of Chicago and for Chicago's Community Legal Counsel. She has been a caseworker for the Cook County Department of Public Welfare.

Education:

Ms. Dotson graduated in 1950 from Ohio Wesleyan University with a Bachelor of Arts Degree in Political Science. She earned her J.D. degree from the Lincoln University School of Law in 1954.

Personal:

Born in Chicago, Illinois Ms. Dotson currently resides in Washington, D.C. Because of her commitment to the special needs of young women, Ms. Dotson has been active in YWCA volunteer work for many years. She serves as a member of the Board of Directors of the National Capital area YWCA.

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BUDGET REQUEST

Ms. DOTSON. Thank you, Mr. Chairman.

As you have noted, our request amounts to a decrease of $574,000. It is our feeling that this decrease will not diminish the effectiveness of our operation inasmuch as our complaint load has stabilized. Second, I think that it is very important to point out the fact that we have managed to increase the productivity of our personnel to the point that they are performing at a greater capacity than they were a few years ago.

Third, taking into account the stabilization of the complaint caseload, the increased productivity, and the effects of our approach which is to encourage and to aggressively seek a dialog with our constituency groups and recipient agencies in an effort to eliminate instances of discrimination at the earliest possible stage, we feel that we can consistently carry out the mission of OCR with the indicated budget request.

PREGRANT REVIEWS

Senator PROXMIRE. In your prepared statement, you point out that in 1986, your office expects to complete approximately 3,500 pregrant reviews of facilities that have applied to participate in the Medicare Program and must receive civil rights clearance.

If such a review reveals or substantiates a compliance problem, your office requires a program recipient to adopt and implement corrective measures.

Ms. DOTSON. Yes, sir.

Senator PROXMIRE. Can you tell us how many of the facilities you reviewed in the latest year for which statistics are available had compliance problems so that we can get some idea of your workload in this area?

Ms. DOTSON. I would prefer to supply that for the record, Senator, because I don't remember offhand. Perhaps, Mr. Kretchmar, who is the Associate Deputy for Program Operations, can give you the specifics.

Mr. KRETCHMAR. In 1984, Senator, we closed 3,287 pregrant reviews. Of those, approximately 1,380 involved situations where some change or followup was required. In many cases, it is new facilities applying for Federal participation for the first time. What we do in that followup mode is make sure that these facilities are aware of their responsibilities and they provide us with data at a future time as to how they are complying.

BLOCK GRANT REGULATION

Senator PROXMIRE. Your office has had the responsibility of enforcing the civil rights portion of block grants to the States since 1981. The budget justification for fiscal year 1986 indicates your intention to issue proposed regulations to implement the nondiscrimination provision of these block grant statutes.

Four years after you were given this responsibility, you now intend to propose regulations. Why did it take you 4 years?

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Ms. DOTSON. Senator Proxmire, I would like to explain that. The Office for Civil Rights of the Department first issued draft regulations for the block grants in February 1983. The process requires that civil rights regulations be cleared by the Department of Justice, and in this case also by the Equal Employment Opportunity Commission. The EEOC and the Department of Justice cleared on those regulations, and they were returned to the Department and submitted to OMB in April 1984, where they are now awaiting final clearance.

Senator PROXMIRE. Two years seems like an awfully long time.

During fiscal year 1985, OCR anticipates issuing proposed regulations to implement the nondiscrimination provisions of the block grant statute. The regulations will not impose any new reporting or data collection requirements beyond those already contained in existing civil rights regulations. Those regulations are not final, they are proposed.

Ms. DOTSON. They are proposed in the sense that when they are issued, there will be an opportunity for comment. What I am saying is that I can't, and the Department can't, even put them out there for comment until such time as they are cleared by DOJ, EEOC, and finally by the Office of Management and Budget.

Senator PROXMIRE. When will they be made final?

Ms. DOTSON. I am not in a position to say when OMB will clear them. They were final insofar as we were concerned, but we have to wait until they clear them.

Senator PROXMIRE. How long have they been awaiting clearance?

Ms. DOTSON. As I recall, since April 1984.

Senator PROXMIRE. So they have been awaiting clearance for almost 1 year?

Ms. DOTSON. That is true, Senator.

COMPLAINT CASELOAD

Senator PROXMIRE. Perhaps the committee should write a letter to OMB and ask why they are delaying the regulations. I hope we will do that. I am sure the chairman will want to write such a letter and I will be happy to join him.

Ms. Dotson, you seem to be falling short of your initial complaint processing goals. Although your office received only 10 more complaints than initially estimated in 1984, your end-of-year inventory was 487, 72 cases more than you projected last year. Can you tell us how that compares to your 1983 end-of-year inventory.

Ms. DOTSON. I am going to defer to Mr. Kretchmar

Mr. KRETCHMAR. Yes; in 1983, our ending inventory was 439 complaints. It went up in 1984.

Senator Proxmite. By how much?

Mr. KRETCHMAR. It went up to 487, which is a rise of approximately 50. Although our productivity overall went up, I would attribute that increase primarily to the very sharp increase in the pregrant reviews as we have mentioned before. Our pregrant workload in 1983 was approximately 2,100 requests, and in 1984, it jumped to 4,000.

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In addition, in 1983, we revised our pregrant procedures to make them more comprehensive. Up until that time, we were focusing only on title VI of the Civil Rights Act, specifically race discrimination, as the subject of our pregrants. In 1983, we added section 504, discrimination on the basis of handicap, and also we are now looking at discrimination with respect to age under the Age Discrimination Act.

So in addition to expanding our pregrants in terms of the jurisdictions, we also experienced almost a doubling of that caseload during that period. Since that time, we have been able to get both inventories under control, and I think we are not projecting any continuing increase in the inventories in either category within the next year or so.

Senator PROXMIRE. Last year, you projected that your end-of-year complaint inventory would drop from 415 cases in 1984 to 390 in 1985. Now you project an increase in that inventory from 487 cases in 1984 to 497 cases in 1985. Putting it another way, your end-of-year inventory will be almost 30 percent higher than your initial projection. Doesn't that mean there is a continuing problem?

Mr. KRETCHMAR. The beginning inventory in 1984 was 439. It rose to 487, which is an approximately 10-percent increase by the end of 1984. We are projecting, by the end of 1985, a very modest increase of 10 additional complaints in our inventory at the end of the year.

Senator PROXMIRE. That is just what I said. You project an increase in inventory from 487 cases at the end of 1984, to 497 cases at the end of 1985, but the total will be 30 percent higher than last year's initial projection, which was 390 in 1985.

Mr. KRETCHMAR. Again, I can only say that the reason for that was the substantial increase in our pregrant review workload. We are projecting for 1986 a reduction in that inventory from 497 at the beginning of the year to 456 at the end of the year.

I would also say that it is possible, because of the nature of the pregrant requests, that there may be a decrease over time in the numbers. The reason the numbers went up substantially is because of the home health care, the hospice programs that were introduced under Medicare, and a very large number of the facilities that we have been looking at were those kinds of facilities.

I am not sure, although our budget shows a fairly constant number, that that increase will persist and that this might represent a surge. If, in fact, the pregrants begin to drop off in the outyears, we can devote more time to decreasing the complaint inventory.

To answer your question, the inventory is under control, and by the end of next year, we should reduce it from what we are projecting at the end of this year by approximately 40 cases.

UNFILLED POSITIONS

Senator PROXMIRE. Ms. Dotson, on page 79 of your justification you indicate that over 15 percent of your permanent positions will be unfilled at the end of 1985, and more than 10 percent of those positions will remain unfilled at the end of 1986.

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In order to make some sort of comparison, I will tell you that the inspector general expects that about 5 percent of his positions will be unfilled at the end of 1985 and less than 1 percent will remain unfilled at the end of 1986.

Why can't your office do a better job of filling those positions?

Ms. DOTSON. No. 1, we might be a bit more penurious in our management. I would like to defer to Mr. Crivella who has that responsibility.

Mr. CRIVELLA. The reduction, Senator, is 23 FTE in 1985, and it goes down 6 FTE in 1986 for a total of 29. The reason that we didn't fill all positions is that we had to get down to a lower FTE level in 1984 and 1985. Consequently, we didn't fill those positions. We are taking an additional 6 FTE cut in 1986, which will bring it down to 396.

Senator PROXMIRE. I understand the arithmetic, but it seems to me that you end up well below that figure. Your justifications show 387 positions filled at the end of 1985, and 386 filled at the end of 1986, so that you plan not to fill as many positions in 1986.

Mr. CRIVELLA. That is correct, sir, and our money is budgeted on that basis. What has occurred is that we must come in this year at the 402 FTE level, which we are currently at. As of yesterday, I was at 401.7.

Senator PROXMIRE. Your budget justification says that total permanent positions for your agency at the end of 1986 will be 430. You tell me that the figure should be 396.

Mr. CRIVELLA. That is authorized positions, and I was talking about FTE, Senator. The authorized positions will be 430, but the FTE will be 396.

POSITIONS AND FTE

Senator PROXMIRE. Why is there such a discrepancy between authorized positions and FTE?

Mr. CRIVELLA. Basically, I could explain that I have quite a few seasonal employees, temporaries, junior fellows, stay-in school, so that an actual body count would be higher, and they are funded in the budget. FTE is a measure of hourly wage.

Senator PROXMIRE. Let me ask Mr. van der Voort to follow up on that.

Mr. VAN DER VOORT. What is the point of having 430 permanent positions assigned to you if you can only use 396 FTE?

Mr. CRIVELLA. I think I will defer to Mr. Hopkins on that.

Mr. HOPKINS. The number of permanent postions is the maximum number of authorized, full-time permanent staff that can be onboard. It is a ceiling in effect. In an organization like the Office for Civil Rights, there is also an FTE ceiling or guideline set which is 396 full-time equivalent employees. This is an average measure over the year of the work force.

An organization whose statutory mission is investigation and enforcement needs to be able to fill jobs, at some point of the fiscal year, over and above the 396 average personnel strength as measured in FTE's.

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For example, if they have 375 full-time permanent jobs filled in August and they have an enforcement crisis in some part of the country, they have to have the flexibility as an enforcement agency to go in and hire 25 or 30 before the end of the fiscal year.

Senator PROXMIRE. Has it been a steady policy on the part of the agency to always keep that much of a cushion between FTE and actual authorized permanent positions so that you will have that flexibility?

Mr. HOPKINS. The rule of thumb for most agencies is about 3 percent for the department. The Social Security Administration has a slightly smaller relationship.

Senator PROXMIRE. Yours is much bigger than theirs.

Mr. HOPKINS. Ours is much bigger than theirs.

Senator PROXMIRE. Is that because of your enforcement duties?

Mr. HOPKINS. It does provide an extra measure of flexibility for a small organization like this.

Senator PROXMIRE. These are permanent positions. If you have any kind of an emergency, you could fill them.

Mr. HOPKINS. If there was an emergency, it provides us with the opportunity to fill on a permanent basis if, in fact, that is the only way that OCR can hire employees quickly. They could come down in a succeeding fiscal year through attrition and still meet the set level of FTE's.

PERMANENT POSITIONS FILLED

Senator PROXMIRE. Let me ask Mr. van der Voort to follow up on that.

Mr. VAN DER VOORT. I have just one question. If, in fact, this is for emergencies, could you tell us, perhaps for the record, how close you have gotten to those permanent position ceilings over the course of 1984, and how close you anticipate you will get in 1985 and 1986. It seems to me that those are completely superfluous positions.

Mr. HOPKINS. We will be happy to do that for the record. I would also point out that the dollars that this committee is presented in this budget request are not based on the 430 level, but based on the 396 full-time employment level, with some additional non-FTE positions included. So you are not being asked to appropriate for the 430.

[The information follows:]

POSITIONS AND FTE

During fiscal year 1984, OCR operated under an Office of the Secretary-wide hiring freeze. OCR was authorized 509 permanent positions during that year. The highest number of permanent positions filled at any time during fiscal year 1984 was 455. Because we cannot know exactly when employees may leave OCR in the future, it is not feasible to project the highest number of permanent positions that may be filled at any time during fiscal year 1985 and fiscal year 1986. To date in fiscal year 1985 the closest that OCR has come to our authorized ceiling of 459 permanent positions has been 411. The only estimates that we can make at this time for fiscal year 1986 are that 387 permanent positions will be filled at the beginning of the year, while 386 such positions will be filled at the end of the year. However, OCR's authorized compensable work-year [FTE] ceiling for each year is lower than authorized positions. All workload

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and resource projections provided in the budget are based on compensable work-years and costs associated with ceiling-exempt employees—not on authorized positions.

AVERAGE SALARY

Senator PROXMIRE. Last year, Ms. Dotson, you estimated that your average GS salary in 1985 would be $31,917. Your current average salary estimate for 1985 is $35,664. That means that your average GS salary in 1985 is almost 12 percent higher than your initial estimate, far more than the January pay raise of 3.5 percent.

Why will average GS salaries grow so sharply in 1985?

Mr. CRIVELLA. I will explain that, Senator. We have for our investigators a career ladder that goes from GS–7 to GS–12. Two-thirds of our staff are out in the field, one-third being here at headquarters, and most of them occupy the career ladder positions. Currently in, I believe, six regions the GS–12 level is the average for our journeymen people.

We hired at the GS–7 level, and over the years they have reached the GS–12 level. The average grade, I believe, is about 11, and I can supply that for the record.

[The information follows:]

AVERAGE GRADE

The average grade projected for fiscal year 1986 is 10.65.

TRUST FUND TRANSFER

Senator PROXMIRE. The portion of your budget using a transfer from the Social Security and Medicare trust funds shows an increase of 70 percent in your fiscal year 1986 request. Does that mean you project an increase in civil rights complaints from participants in those programs?

Ms. DOTSON. No; it doesn't. The increase that we have in the transfer is an effort to reflect what the actual work of OCR has been, to bring it up to date.

Senator PROXMIRE. Can you describe the kinds of problems that occur in these programs, and why they require an increase transfer of trust funds.

Ms. DOTSON. Perhaps I didn't clearly explain what I meant in response to your question. The increase in the transfer is not intended to expand the Medicare workload.

Mr. CRIVELLA. No; it is just to bring it more in line with what we have been doing. It has been approximately 20 percent. We are requesting an increase of $1,650,000 over last year when we received $2,350,000.

Senator PROXMIRE. Let me ask you, Mr. Crivella, what have you been doing in those programs to account for the increase?

Mr. CRIVELLA. I think the Office of the Secretary decided that the amount should be more in line with what we have been doing with the trust funds.

Senator PROXMIRE. The question is, what have you been doing with the trust funds?

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Mr. HOPKINS. The Social Security Act does authorize payments from the trust funds for certain administrative services that benefit the trust funds. In the case of the Office for Civil Rights, this is an organization that now provides somewhere in the range of $4 to $5 million annually in investigations, principally in hospitals. They look at enforcement problems in hospitals, at discrimination in hospitals in response to complaints, and also compliance.

Senator PROXMIRE. That is fine. That is all I wanted to know.

Will you give me, for the record, the specific investigations in hospitals.

Mr. HOPKINS. We will be glad to do that.

Senator PROXMIRE. We want to thank you.

[The information follows:]

HOSPITAL INVESTIGATIONS

During fiscal year 1984, 369 hospitals, 1,392 nursing homes, 1,902 home health agencies, and 340 other health agencies were subjects of OCR Medicare pregrant reviews. Hospitals were also the subject of 82 compliance reviews, 602 project reviews, and 348 complaint investigations. Only pregrant reviews focus entirely on certification of the civil rights compliance of prospective Medicare providers. It should be noted that hospitals and other Medicare providers that are subjects of all types of compliance activities may also receive funding from other HHS programs such as Medicaid.

LETTER FROM SENATORS WEICKER AND PROXMIRE TO DAVID STOCKMAN AND HIS RESPONSE

[CLERK'S NOTE.—The following letters were received after the hearing and will be included in the record at this point.]

LETTER FROM SENATORS LOWELL WIECKER, JR., AND WILLIAM PROXMIRE

JUNE 3, 1985

HON. DAVID A. STOCKMAN,
Director, Office of Management and Budget, Executive Office Building, Washington, DC.

DEAR MR STOCKMAN: Earlier this year in the course of this subcommittee's hearings on the fiscal year 1986 budget for the Department of Health and Human Services' Office for Civil Rights we discussed certain proposed regulations affecting the various State block grant programs.

More specifically, we were told that regulations to safeguard the civil rights of block grant recipients had been submitted to the Office of Management and Budget [OMB] in April 1984. In other words, they appear to have been mired in your office for over a year. We find it difficult to understand why regulations of such immediate benefit to groups historically subjected to discriminatory action have been delayed for such a long period of time.

We would like to learn from you why the regulations have taken so long to clear OMB and when we might expect final action by your office. We would appreciate receiving your response by June 21 so that it may become a part of our fiscal year 1986 hearing record.

Sincerely,

LOWELL WEICKER, JR.,
Chairman, Labor-HHS-Education Appropriations Subcommittee.
WILLIAM PROXMIRE,
Ranking minority member.

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LETTER FROM DAVID A. STOCKMAN, DIRECTOR, OFFICE OF MANAGEMENT AND BUDGET, EXECUTIVE OFFICE OF THE PRESIDENT

JULY 1, 1985.

HON. LOWELL WEICKER, JR.,
Chairman, Subcommittee on Labor, Health and Human Services, Education, Committee on Appropriations, U.S. Senate, Washington, DC.

DEAR MR. CHAIRMAN: Thank you for your letter of June 3, 1985, with respect to a notice of proposed rulemaking implementing the nondiscrimination provisions in the Department of Health and Human Services' block grant statutes. Since the administration proposed and worked hard to secure the enactment of those nondiscrimination provisions, I share the concern you have expressed.

Please be assured that this administration is committed to issuing regulations that afford the strongest possible protection against discrimination and are consistent with the principles of federalism. I have instructed my staff to work with HHS to achieve closure on this matter at the earliest possible date, and will keep you informed of progress in this regard.

Sincerely,

DAVID A. STOCKMAN,
Director.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator PROXMIRE. Thank you very much. There will be additional committee questions which we would appreciate if you would answer for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

TRUST FUND TRANSFER/SHIFT IN FOCUS

Question: The portion of your budget using a transfer from the Social Security and Medicare trust funds has increased by 70 percent in your FY 1986 request. Does this mean an increase in civil rights complaints from participants in these programs?

Answer: No, it doesn't. The increase in the amount of the trust fund transfer is intended to bring the amount more in line with the proportion of our workload and staff effort that has been devoted to Medicare-related facilities during the past few years. During FY 1985 and FY 1986, trust fund compliance work will continue to represent approximately 20 percent of OCR's total workload.

Question: Describe the kinds of problems that occur in these programs and why they require an increase in effort by your office?

Answer: First of all, as I've already stated, our effort in this area will remain the same as in FY 1984 and FY 1985. The trust fund transfer itself will be increased to bring the funding in line with the level of effort that we have been devoting to this area during the past few years. As far as the problems are concerned, they are not much different from those that arise in other federally assisted health programs such as Medicaid. This is because, for the most part, we are dealing with the same types of facilities -- hospitals, nursing homes, home health agencies, etc. Problems may include admissions and notification policies, differential placement, effective communications with the hearing or sight-impaired, provision of auxiliary aids, communication with persons of limited English proficiency, lack of assurances, and failure to have completed a Section 504 self-evaluation.

Question: Your budget and Full Time Equivalent (FTE) complement has decreased in FY 1985 and FY 1986. If you are increasing your effort in the trust fund programs, it follows that you are decreasing your effort elsewhere. In which areas have you decreased your effort and why?

Answer: The increase in the trust fund transfer does not represent a shift in focus toward problems in social security and Medicare programs. Rather, the increase is intended to bring the amount more in line with the proportion of our workload that has been devoted to Medicare-related facilities during the past few years. During FY 1985 and FY 1986, trust fund compliance work will continue to represent approximately 20 percent of OCR's total workload.

BLOCK GRANT/DELAY IN ENFORCEMENT

Question: Your office has had the responsibility of enforcing civil rights portions of block grants to the States since 1981. The budget justification for FY 1986 indicates your intention to issue proposed regulations to implement the nondiscrimination provision of these block grant statues. Five years -- after you were given this responsibility -- you now intend to propose regulations. Why did it take you five years?

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Answer: The Office for Civil Rights first issued draft regulations for the block grants in February of 1983. Civil Rights regulations, pursuant to Executive Order, must be cleared by the Department of Justice. In this case, the Equal Employment Opportunity Commission was also involved in the review. Following EEOC and Department of Justice review and clearance the regulation was returned to us. The Secretary transmitted the EEOC and Justice-cleared regulations to the Office of Management and Budget in April of 1984. The regulations are currently awaiting final OMB clearance.

Question: Assuming you follow through on your intention, when will you begin to enforce these laws?

Answer: We have been active on many fronts in addition to drafting regulations. For example, we have developed procedures covering block grant programs and have trained regional staff on their use. We have worked with States to implement the governor's role in gaining voluntary compliance in block grant cases. Our regional offices have worked with State officials to establish procedures and a contact point to assure that any findings of noncompliance can be brought to the attention of the governor's liaison promptly for actions in accordance with the provision giving governors 60 days to secure voluntary compliance. We have provided technical assistance to the States and will continue to provide the States with policy guidance, procedural instructions, and training. Additionally, in FY 1984 OCR initiated block grant compliance reviews in 10 States and processed 25 complaints of programs funded solely by block grants.

FULL TIME EQUIVALENTS vs. COMPLAINTS

Question: Once again you are proposing to reduce the number of employees in the Office for Civil Rights. In 1984 you had 437 Full Time Equivalent (FTEs), and in 1986 you are proposing 396 FTEs, a cut of 41 or nearly 10 percent in two years. When are these reductions going to be taken?

Answer: OCR used 437 full time equivalent (FTEs) in Fiscal Year 1984. This will drop to 402 authorized FTE in Fiscal Year 1985 and to 396 authorized FTE in Fiscal Year 1986. OCR is using about 402 FTE on an annual basis at the present time.

Question: How will this impact on the time it will take to process a complaint?

Answer: We do not believe the FTE reductions in Fiscal Year 1985 and in Fiscal Year 1986 will affect the time it takes to process complaints. Under the budget OCR will allocate sufficient staff to keep pace with the complaint workload.

Question: How long did it take to process a complaint in 1981?

Answer: Our records show that it took OCR 116 days on average to close a complaint case in Fiscal Year 1981.

Question: How long does it take now, in 1985?

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Answer: In Fiscal Year 1984 it took OCR an average of 148 days to complete a complaint case. The increase from FY 1981, is mainly attributable to our emphasis on resolving older cases in the inventory.

DECLINING COMPLAINTS vs. ATTITUDE

Question: You have been telling this Committee for the past two years that the numbers of complaints have declined. Is this correct?

Answer: The number of new complaints dropped sharply in Fiscal Year 1982 and has stabilized since that time. OCR received 1,165 new complaints in Fiscal Year 1984 compared to a high of 1,704 complaints in Fiscal Year 1981.

Question: I am sure Ms. Dotson, that you would agree that discrimination and other fruits of racism are still very much present in our society. Have you initiated any sort of study or review to identify the reasons for declining complaints?

Answer: We have not initiated any formal study to explore why the number of new complaints has stabilized in the last few years after the sharp decline in Fiscal Year 1982. Several factors may be behind it. For example, during the past several years OCR has emphasized a "preventive" approach to civil rights enforcement designed to encourage voluntary compliance. Within this overall approach resources have been committed to encourage health care facilities like hospitals to adopt procedures and standards that will improve access for handicapped persons. In Fiscal Year 1984, 374 of 413 hospitals subject to project reviews voluntarily changed practices or policies as a result of the reviews and follow-up technical assistance. It is reasonable to assume that in such facilities and in other facilities that OCR has worked with, the potential for compliants diminishes. On the other hand, I agree that problems of discrimination exist and that OCR has a full job in ensuring compliance among the large universe of federally assisted programs. Although the complaint workload has not risen again to the level reached in Fiscal Year 1981, it has not declined subetantially either since 1982.

MEDICARE

Question: You have indicted that your office is making a greater effort in the Medicare programs. What sort of problems have you been dealing with?

Answer: As I have stated, our Medicare-related workload in FY 1986 will remain the same as in FY 1984 and FY 1985. The problems that arise in the Medicare program are not much different from those that arise in other federally assisted health programs such as Medicaid because mainly we are dealing with the same types of facilities -- hospitals, nursing homes, home health agencies, etc. Problems include, but are not limited to: admissions policies and practices, differential placement, effective communication with the hearing or sight-impaired, and provision of auxiliary aids.

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Question: How have your efforts reduced discrimination in these programs?

Answer: Examples of results of our efforts in these programs include Medicare-related facilities that have: established nondiscrimination policies and provided notice of such policies to beneficiaries and potential beneficiaries; undertaken Section 504 self-evaluations; designated Section 504 coordinators; and, provided telecommunications devices and other auxiliary aids to enhance service delivery to the hearing and sight-impaired.

Question: Should we be applying more effort and greater resources to this area?

Answer: In our judgment the budget is adequate to handle the pregrant review workload and to meet other compliance responsibilities that involve Medicare providers.

COMPLIANCE

Question: You are putting a greater proportion of declining resources in the voluntary compliance program. Can you provide us with an example of how a pregrant review enhances compliance?

Answer: An excellent example of pregrant review activity is the model agreement negotiated with the Hillhaven Corporation, owner of hundreds of nursing homes. The agreement provides for nationally consistent corporate policies on nondiscrimination and on communication with the hearing-impaired. Working with corporate headquarters has had substantial payoff. In another case involving corporate facilities, a single pregrant review of a California home health care provider resulted in the establishment of corporate policies covering large-print forms for the visually impaired and TTYs for the hearing-impaired.

Question: Have you received complaints from programs that underwent pregrant reviews?

Answer: Yes, we have received such complaints. OCR carries out pregrant reviews of facilities seeking certification under the Medicare program. During FY 1984 OCR completed 3,287 pregrant reviews. OCR received subsequent complaint allegations regarding thirteen of the facilities subjected to review. Ten of the allegations were within OCR's jurisdiction. Therefore, through March 1985, allegations of discrimination that could be investigated were made against only 0.3 percent of all facilities for which a pregrant review had been completed during FY 1984. Because pregrant reviews address general policies, procedures, and service practices, it remains possible that a specific instance may arise, after a review, in which an individual complainant alleges that a facility has ignored, misinterpreted, or unfairly applied an existing policy or practice.

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SUBCOMMITTEE RECESS

Senator PROXMIRE. The subcommittee will stand in recess until tomorrow, Wednesday, March 27, at 9:30 here in room SD-116. At that time we will hear testimony from the following: the Social Security Administration, the Office of Child Support Enforcement, the Office of Refugee Resettlement, and Health Care Financing Administration.

Thank you very much.

[Whereupon, at 12:20 p.m., Tuesday, March 26, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, March 27.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

WEDNESDAY, MARCH 27, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:35 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lowell Weicker, Jr. (chairman) presiding.

Present: Senators Weicker, Andrews, Domenici, Proxmire, Byrd, Chiles, and Harkin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SOCIAL SECURITY ADMINISTRATION

OFFICE OF CHILD SUPPORT ENFORCEMENT

OFFICE OF REFUGEE RESETTLEMENT

STATEMENTS OF:

MARTHA A. McSTEEN, ACTING COMMISSIONER OF SOCIAL SECURITY ADMINISTRATION

R. STEVE RITCHIE, DIRECTOR, OFFICE OF CHILD SUPPORT ENFORCEMENT

PHILLIP N. HAWKES, DIRECTOR, OFFICE OF REFUGEE RESETTLEMENT

ACCOMPANIED BY:

NELSON J. SABATINI, ACTING DEPUTY COMMISSIONER FOR MANAGEMENT AND ASSESSMENT

ARTHUR F. SIMERMEYER, ACTING DEPUTY COMMISSIONER FOR SYSTEMS

JO ANNE B. ROSS, ASSOCIATE COMMISSIONER FOR FAMILY ASSISTANCE

SHERWIN T. MONTELL, DIRECTOR, OFFICE OF FINANCIAL RESOURCES

DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

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INTRODUCTION OF ASSOCIATES

Senator WEICKER. The subcommittee will come to order.

Today we will hear testimony from the Social Security Administration, the Office of Child Support Enforcement, and the Health Care Financing Administration.

To expedite matters, the Office of Child Support Enforcement is included with the panel of Social Security Administration witnesses, even though it reports directly to the Secretary.

The lead witness is Martha McSteen, Acting Commissioner of Social Security, and if you will introduce your associates, please proceed as you wish.

Mrs. MCSTEEN. Thank you, Mr. Chairman. On my right Mr. Arthur Simermeyer, Acting Deputy Commissioner for Systems; Jo Anne Ross, Associate Commissioner for Family Assistance; and Phil Hawkes, Director of the Refugee Program. On my left are Nelson Sabatini, Acting Deputy Commissioner for Management and Assessment, and the newest and now permanent appointee, Steve Ritchie who heads up the Office of Child Support Enforcement; and Dennis Williams, who is the Acting Deputy Assistant Secretary for Budget.

PREPARED STATEMENT

Senator WEICKER. Proceed, and we will insert your complete statement in the record.

[The statement follows:]

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STATEMENT OF MARTHA A. MCSTEEN

Mr. Chairman and members of the Committee, I am pleased to be here today to present the fiscal year 1986 appropriations requests of the Social Security Administration and the Office of Refugee Resettlement. These requests total $26.6 billion in budget authority.

Summary of Budget Requests before the Committee

I would like to summarize the fiscal year 1986 requests before your Committee that require appropriations action.

—$497.0 million for Payments to Social Security Trust Funds. Through this account the trust funds are reimbursed for the costs of certain benefits and administrative expenses chargeable to Federal funds.

—$997.9 million for Special Benefits for Disabled Coal Miners. These funds cover benefit payments and administrative expenses for that portion of the black lung program administered by SSA.

—$10.0 billion for the Supplemental Security Income program. This request includes SSI benefits and reimbursement to the Social Security trust funds for the administrative costs of the SSI program.

—$8.8 billion for the Assistance Payments program. This appropriation includes the Federal share of the benefit costs of the Aid to Families with Dependent Children program, and funds for Federal policy direction and guidance in the administration of the AFDC program. Child Support Enforcement collections are included in this account as an offset to AFDC benefit payments.

—$2.1 billion for the Low Income Home Energy Assistance Program. This program provides assistance to low income households in meeting the costs of home energy.

—$316.6 million for Refugee and Entrant Assistance. This program reimburses States for the costs of providing direct cash and medical assistance to needy refugees and Cuban-Haitian entrants, as well as English language training, vocational training and other social services.

—$3.9 billion for the Limitation on Administrative Expenses. This request provides resources needed to administer the old-age and survivors and disability insurance programs. It also includes funds to finance costs of certain administrative functions performed for the Medicare program by the

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Social Security Administration, and it includes administrative funds for the Supplemental Security Income program and several smaller activities. The trust funds are reimbursed for the administrative costs of the SSI and other non-trust funds programs through appropriations to other accounts.

Social Security Administration Goals and Objectives

Early in 1984 SSA announced four major goals which form the foundation for all activities performed in the Agency. They are:

- To provide timely and accurate payment of benefits,
- To administer the program efficiently and effectively,
- To provide courteous, sensitive and dignified service to the public, and
- To strive toward a positive work climate for all employees.

In support of these goals, we developed eight major objectives for SSA through fiscal year 1988. We are achieving these objectives through a project management approach. The eight objectives are:

- Effectively manage workloads.
- Modernize the Social Security claims system.
- Redesign the annual wage reporting system.
- Manage the impact of automation on SSA's personnel and organization.
- Provide a reliable management information system.
- Improve internal program instructions and information.
- Effectively manage a national disability program.
- Issue clear notices to beneficiaries and other members of the public.

Accomplishments of Systems Modernization

In February 1982, the Administration announced a multi-year Systems Modernization Plan to move the Social Security Administration's antiquated computer systems into a modern, efficient state-of-the-art system. This transition will result in automation of large volumes of work now done manually. The Administration made a commitment to fund needed hardware and software, and the Congress has supported this effort. Significant improvements already have been made to upgrade SSA's telecommunications system, to improve software, to move to direct access data storage, and to obtain needed hardware. These changes have reduced employment needs and at the same time improved service to the public. Reductions in employment have been accomplished without reduction-in-force.

Largely as a result of systems and procedural changes we have reduced large

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backlogs of work and we are providing a faster response time to the public. Some examples of these improvements are:

- Overall processing time for a retirement and survivors insurance claims declined to 22.8 days in 1984, an improvement of 5.5 days compared to the year before. Processing time for SSI aged claims declined by over 5 days compared to a year earlier, and processing times for disability claims have remained fairly steady.
- SSA processed the bulk of the 130 million 1983 annual wage reports 6 weeks quicker than the prior years' processing time.
- We improved the automation rate and timeliness of the annual earnings recomputation process to give beneficiaries credit for earnings after retirement. Until recently, SSA had been far behind in the posting of wage credits for this work and in the recomputation of benefits based on this work. The automation rate is now over 70 percent—about 20 percent higher than it was in mid-1983.
- We have speeded up issuance of Social Security account numbers so that average time elapsed from application to receipt of a card is 11 days instead of 6 weeks.
- SSA has improved its telecommunications system linking the field offices with the central computer complex. Employees spend less time accessing the system, and beneficiaries are provided quicker responses to inquiries.
- In the Program Service Centers, we have reduced retirement and survivors insurance claims backlogs by 36 percent, from 144,000 in fiscal year 1982 to 92,000 in fiscal year 1984.
- In the Office of Disability Operations, we have reduced disability insurance claims backlogs by 23 percent, from 62,000 in fiscal year 1982 to 48,000 in fiscal year 1984.
- We have reduced the pending level of earnings record requests from a high of 166,000 in February 1983 to 81,000.

Long-Term Productivity Improvement Plan

More significant data processing enhancements will occur in the next 6-year period, fiscal year 1985 through fiscal year 1990, as a result of Systems Modernization Plan projects, and other management improvements. The Administration's objective is to realize the benefits of substantial

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investments in automation while improving service to the public. Savings are expected from:

—modernization of the retirement, survivors and disability insurance claims system;

—modernization of the supplemental security income claims system;

—expansion of district office final authorization to cases currently referred to the program service centers for final authorization and payment of initial claims;

—implementation of a project to improve the efficiency and cost effectiveness of SSA's program delivery structure;

—reductions in SSA staff/support positions where employees are not involved in direct service to the public or processing of claims and post-entitlement workloads; and

—other ongoing systems enhancements and procedural improvements.

In order to provide for a smooth transition to modernization, without adverse effects on either employees or service to the public, the productivity improvement plan will provide for retraining and relocation of employees as the new processes are implemented. To assist SSA in this effort, the President's budget proposes a change in the fiscal year 1986 appropriations language of the Limitation on Administrative Expenses account, to permit use of the contingency reserve to meet unpredictable costs resulting from the impact of automation on the workforce.

Disability Benefits Reform Act of 1984

I would like to mention one other key issue—implementation of the Disability Benefits Reform Act of 1984. In April 1984, the Secretary of Health and Human Services announced a moratorium on periodic continuing disability reviews (CDR's) so that SSA could resolve recurring problems surrounding these continuing reviews, which were mandated by the Disability Amendments of 1980, and work with Congress on pending legislation. In October 1984, legislation passed both Houses of Congress, and on October 9, 1984 the Disability Benefits Reform Act of 1984, was signed by the President. Since then SSA has been working to draft regulations to implement the major provisions of the legislation and has begun to release them for comment. Final rules on the review provisions are needed before the review process resumes. Estimates for the disability

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program reflect resumption in fiscal year 1985 of reviews of continuing eligibility.

Due to uncertainties about workloads resulting from this legislation and the final form of regulations to implement the Disability Benefits Reform Act, we cannot accurately assess resource needs at this time. For example, it is difficult to predict how many individuals will apply for reinstatement of benefits under the new medical improvement standard, or how many will reapply for benefits because of the revised mental impairment standards. In view of these uncertainties and possible unanticipated costs related to the impact of automation on the workforce, we are requesting an increase in fiscal year 1986 in the contingency reserve in SSA's Limitation on Administrative Expenses account. SSA requests that the contingency reserve be increased rather than budget large resources for workloads that may not materialize or can be absorbed due to lower than budgeted workloads in other areas. This will ensure that adequate resources are available, if needed, for implementation of the disability legislation and for other purposes.

FY 1985 Supplemental Requests

We are proposing supplemental appropriation actions for fiscal year 1985 for the Payments to the Social Security Trust Funds and the Limitation on Administrative Expenses. The $3.5 billion supplemental request for Payments to Social Security Trust Funds represents our adjustment that will be required to update the financing of military service credits granted for service performed before 1957, as required by the Social Security Amendments of 1983.

For the Limitation on Administrative Expenses we request the transfer of $10,000,000 from unobligated field office construction funds, which are no longer needed for that purpose, to increase funds available for telephone systems acquisitions. No new budget authority is requested.

Payments to Social Security Trust Funds

The appropriation request for Payments to Social Security Trust Funds totals $497,008,000 and covers four Federal fund payments to the Social Security trust funds.

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Military Service Credits

The request before this Committee for Military Service Credits in FY 1986 is for $356,000,000. This is the estimated amount of employer-employee OASDI payroll taxes for calendar year 1986 payable on the deemed wage credits of military service personnel. The payment has the same effect on the trust funds as if the deemed wages had been taxed as covered wages.

The request does not include funds for the cost of gratuitous wage credits granted for military service performed prior to 1957. Annual payments for this purpose have been replaced by a lump sum payment under the terms of the Social Security Amendments of 1983. Funding for the periodic adjustment of the lump sum payment is requested as a supplemental appropriation in FY 1985.

Special Payments to Certain Uninsured Persons

The second requested payment of $90,264,000 is to reimburse the Old-Age and Survivors Insurance trust fund for special benefits paid during FY 1984 to certain uninsured persons aged 72 years and over. The payments are made to individuals who did not have a chance to work long enough under Social Security to become insured. These beneficiaries, a declining population, were not eligible for regular monthly Social Security benefits, primarily because they retired before enactment of the Social Security Act or before their occupations were covered under Social Security.

The FY 1986 request for Special Payments to Certain Uninsured Persons is $14,714,000 below the FY 1985 estimate. The population receiving special payments is a closed group of very aged persons which declines annually. As of September 30, 1984, 42,000 persons were receiving benefits chargeable to the general funds under this provision as compared to 53,000 a year earlier.

Reimbursement for Pension Reform Administrative Costs

The third requested payment is for $744,000 to reimburse the Old-Age and Survivors Insurance trust fund for the Federal funds share of the cost of

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administering pension reform responsibilities assigned to the Social Security Administration under Public Law 93-406, the Pension Reform Act. The reimbursement is for the cost of furnishing information on deferred vested pension rights to pension plan participants or their survivors. The FY 1986 estimate for pension reform administrative costs reflects a continuation of SSA's FY 1985 pension reform activities.

Unnegotiated Checks

The fourth and final requested payment of $50,000,000 is to reimburse the trust funds for the value of benefit checks that remain uncashed after 6 months, plus interest. The Social Security Amendments of 1983 provides for reimbursements based upon estimates developed jointly by the Departments of Health and Human Services/Treasury until a system capable of identifying the exact number and amount of uncashed benefit checks is implemented by the Treasury Department.

Amounts obligated from this appropriation, as well as prior appropriations under this authority, will be finalized upon completion of a joint study of all Government checks outstanding at the close of FY 1983. The study is scheduled for completion in FY 1985, and will serve as the basis for computing monthly transfers until Treasury modifies its system to automatically distinguish Social Security checks from all other Government checks.

FY 1985 Supplemental

The $3.5 billion supplemental request for Payments to Social Security Trust Funds represents the current estimate of the maximum adjustment that will be required to update the financing of military service credits granted for service performed before 1957. Under the Social Security Amendments of 1983, a one-time, lump-sum payment was made to the trust funds in an amount estimated at the time to be the present value of future benefits arising from gratuitous wage credits granted by the law for pre-1957 military service. The Amendments also provided for adjustment for the estimate every five years, beginning in 1985, to account for recent experience. In order to ensure that

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the re-estimate is based on the most current data available, including the 1985 Trustee's Report, we plan to make the redetermination at the end of September. The actual transfer of funds will occur at the end of October. We are also requesting that these funds remain available through December 31, 1985 to cover any delays in this schedule.

Special Benefits for Disabled Coal Miners

This FY 1986 appropriation request for Special Benefits for Disabled Coal Miners totals $727,908,000 and is financed from general revenues. This is in addition to the $270,000,000 which Congress provided last year as a FY 1986 advance appropriation to fund first quarter benefit payments. Therefore, the total FY 1986 appropriation is $997,908,000. It includes $979,000,000 for FY 1986 benefit payments, $6,519,000 for administrative costs, and $12,389,000 to cover FY 1985 benefit payments funded from the FY 1986 request through the drawdown provision of the appropriation. It does not include reimbursable work done for the Department of Labor, which is budgeted for by that Agency.

Program Authorization

The black lung program is authorized by title IV of the Federal Mine Safety and Health Act of 1977, which provides for payment of monthly cash benefits to coal miners who are totally disabled because of pneumoconiosis, commonly referred to as black lung disease, and to widows and certain other dependents of miners who were entitled to these benefits or whose deaths were due to this disease.

Responsibility for Administration

The Social Security Administration is responsible for processing and paying claims for miners' benefits filed from December 30, 1969 through June 30, 1973 and claims for survivor benefits filed through December 31, 1973 or within 6 months after the death of a miner or widow already on the beneficiary rolls maintained by SSA. SSA pays benefits and maintains the beneficiary rolls for the lifetime of all persons who filed with SSA during its jurisdiction.

Since June 30, 1973 SSA has continued to take miners' claims--but as an agent of the Department of Labor, which is responsible for adjudication and payment

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of these claims. Costs incurred by SSA in taking these claims are reimbursed by the Department of Labor.

The beneficiary rolls for which SSA has responsibility will continue to decline gradually in years to come as the result of the death of miners and the death or remarriage of widows. At the mid-point of FY 1986, 288,000 beneficiaries will be receiving monthly benefits. This is a decrease of 20,000 from the 308,000 beneficiaries who will be receiving payments at the mid-point of FY 1985.

Explanation of Change for FY 1986 Request

We estimate benefit payment obligations to be $979,000,000 in FY 1986--$50,000,000 less than in FY 1985. The President's budget estimates assume a 5.0 percent decrease in Federal civilian pay scales beginning January 1986. Although black lung benefits are tied, by law, to Federal civilian pay scales, the FY 1986 request also includes appropriation language which exempts black lung benefit payments from this reduction. Therefore the budget proposes that black lung benefit rates be preserved at the FY 1985 level until Federal pay scales provide a higher benefit level.

The decrease in total benefits is due to a reduction of $57,000,000 for the lower number of black lung beneficiaries, a reduction of $2,000,000 for slightly lower average monthly payments for beneficiaries in current pay, and a partially offsetting increase of $9,000,000 due to the full year effect of the January 1985 benefit increase of 3.5 percent.

Our budget request of $6,519,000 for FY 1986 black lung administrative expenses is $1,001,000 lower than the current estimate for FY 1985. This is based on a reduction in ongoing workloads from the decline in the number of beneficiaries on the rolls.

Advance Appropriation

The budget request includes an advance appropriation of $270,000,000 for the first quarter of FY 1987. This is the same level as requested last year for

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the first quarter of FY 1986. This request insures that benefit payments will continue without interruption into the next fiscal year.

Supplemental Security Income

The Supplemental Security Income (SSI) appropriation provides funds through direct cash assistance to eligible aged, blind and disabled recipients to help finance their basic needs. The appropriation request for FY 1986 is $7,692,589,000 in addition to the $2,345,759,000 already appropriated for the first quarter of FY 1986 to bring the total appropriation to $10,038,348,000. This includes $9,112,868,000 for Federal benefits to aged, blind and disabled recipients, including $176,868,000 to be drawn down for FY 1985 needs, $6,800,000 for beneficiary rehabilitation services; $918,690,000 for payments to the trust funds for administrative costs. Also requested is $2,339,250,000 as an advance appropriation for SSI benefits in the first quarter of FY 1987.

Federal Benefit Payments

The SSI program ensures a minimum monthly level of income to eligible aged, blind and disabled individuals. An individual's income, resources and living arrangements are evaluated to determine the actual amount of SSI payment. Payments are delivered through monthly benefit checks.

The average monthly number of SSI recipients of Federal benefits is projected to increase from 3,708,000 in FY 1985 to 3,743,000 in FY 1986, an increase of 35,000. This increase is due to projected growth in the number of blind and disabled SSI recipients partially offset by a slight decrease in the projected number of aged SSI recipients.

The FY 1986 request for Federal benefit payments, excluding funds drawn down for FY 1985, is $8,936,000,000 or $380,000,000 higher than the FY 1985 level. This increase is needed to fund:

—The 4.1 percent cost-of-living increase projected for January 1, 1986 and
—The projected increase in the number of blind and disabled recipients.

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Beneficiary Rehabilitation Services

SSA provides funds to reimburse vocational rehabilitation agencies for costs incurred in successfully rehabilitating SSI recipients and in instances of discontinuation of benefits prior to completion of vocational rehabilitation. We estimate that $4.8 million will be required for vocational rehabilitation in FY 1986. This is $1.8 million more than the FY 1985 request. In addition, we are requesting $2.0 million, the same amount as in FY 1985 for the referral and monitoring of SSI recipients who are drug addicts and alcoholics.

Payments to the Trust Funds for Administrative Costs

The SSI and Social Security programs are administered on an integrated basis for purposes of economy and efficiency. The Social Security Act authorizes advances from the Social Security trust funds to pay the administrative costs of the SSI program through the Limitation on Administrative Expenses. The advances are fully repaid from the SSI appropriation. SSA maintains a detailed cost allocation system, which has been audited by the General Accounting Office, to ensure that the trust funds are made whole (with interest, if appropriate) for the administrative expenses of the SSI program. The FY 1986 request for this activity is $918,690,000.

Advance Appropriation

The budget request includes an advance appropriation of $2,339,250,000 for the first quarter of FY 1987. This request insures that benefit payments will continue without interruption into the next fiscal year.

Assistance Payments

The Assistance Payment appropriation provides funds through grants to States to pay for the Federal share of State-administered cash maintenance assistance payments to needy families with absent or unemployed parents and dependent children. Although the Social Security Administration is responsible for the programs covered by this appropriation, no trust fund money is used for assistance payments purposes.

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The appropriation request for FY 1986, which reflects $180,000,000 in savings from proposed legislation, is $6,678,578,000. This is in addition to the $2,095,000,000 which Congress provided last year as a FY 1986 advance appropriation to fund first quarter grants to States. Therefore the FY 1986 appropriations total $8,773,578,000. The total includes $8,737,721,000 for maintenance assistance, including $620,316,000 to be drawn down for FY 1985 needs; $2,925,000 for research and evaluation; and $32,932,000 for Federal administrative expenses.

At this time we also are requesting an advance appropriation of $2,193,754,000 to fund first quarter FY 1987 grants. This request also reflects savings from proposed legislation. The advance appropriation will provide funds in FY 1986 for issuing advance grants for the first quarter of FY 1987. Such a procedure enables States to continue program operations without interrruption and to plan in advance.

Maintenance Assistance

The FY 1986 request for the Federal share of the maintenance assistance activities, excluding funds drawn down for use in FY 1985, is $8,117,405,000. The request includes:

—$6,953,000,000 for the Federal share of Aid to Families with Dependent Children (including a reduction for offsetting child support collections of $319,000,000 and a reduction for offsetting fiscal liabilities of $414,000,000).

—$13,743,000 for assistance to aged, blind and disabled adults in Puerto Rico, Guam and the Virgin Islands; the Supplemental Security Income program does not cover these jurisdictions.

—$70,100,000 for the Federal share of emergency assistance to needy families with dependent children.

—$1,073,416,000 for State administration and training. This includes $928,416,000 for regular State administration and reflects a legislative

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proposal to maintain this funding at the FY 1985 level. It also includes $145,000,000 for the State administrative costs of the legislative proposal to provide work opportunities to employable applicants and recipients.

—$6,077,000 for administration and training costs in Puerto Rico, Guam and the Virgin Islands.

—$1,069,000 for assistance to repatriated U.S. Nationals returning from foreign countries who have been certified by the Department of State as destitute or ill.

The FY 1986 request for these maintenance assistance activities is $128,155,000 lower than the FY 1985 level for the same activities. This decrease is the net result of several factors of decrease and increase, primarily in the AFDC and State administration and training costs activities. Significant decreases in the Federal share of program costs result from the following factors:

—A decrease of $271 million from the FY 1985 level as a result of savings from legislation proposed for enactment in FY 1986 which would require all employable adult AFDC applicants and recipients to participate in job search and other work activities, and would improve targeting of AFDC benefits.

—Increased savings of $241 million from the collection of fiscal liabilities from the States for error rates higher than the mandated targets for the FY 1983 and FY 1984 reporting periods.

—Increased savings of $21 million in Child Support Enforcement collections resulting from increases in the child support enforcement caseload and changes in State practices mandated in the Child Support Enforcement Amendments of 1984.

Significant increases in AFDC and State administration and training, are:

—AFDC increases $163 million as a result of economic and demographic factors including: an increase in average benefits due to inflation which is

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reflected in higher State standards of need; an increase in the number of families headed by females, a major factor in the AFDC caseload; and an offsetting small decrease in the unemployment rate.

—AFDC increases by $96 million due to a change in Federal matching rates for payments to State governments for AFDC recipients. In accordance with formulas specified in titles IV and XIX of the Social Security Act, the revised FY 1986 Federal matching rates are expected to average 54.4 percent of benefit payments, compared with an estimated 53.7 percent in FY 1985.

—State and local administration increases by $145 million primarily as a result of increased State administrative workloads to implement the Administration's legislative proposal to require all applicants and recipients to participate in job search and all employable recipients to participate in work programs. These costs are more than offset by savings of $197 million in AFDC benefits generated by this proposal. No further increases are projected for State administration and training costs because of the legislative proposal to maintain this funding at the FY 1985 level.

Research and Evaluation

We are requesting $2,925,000 for research and evaluation grants and contracts under sections 1110 and 1115 of the Social Security Act, an increase of $350,000 over the FY 1985 level. The aim of these projects is to improve the management of the AFDC program and to assess policies which promote work experience for recipients and thus reduce welfare dependency. Although most of the money is for research and demonstration projects related to the AFDC program, some of the funds are used for Social Security and SSI extramural research grants and contracts.

Federal Administrative Expenses

The FY 1986 request includes $32,932,000 for Federal administrative expenses, a decrease of $2,134,000 from the FY 1985 level, and 642 full-time equivalents, a decrease of 39 from FY 1985. An increase of $1,129,000 for mandatory costs such as the costs of the full-year effect of the January 1985

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pay raise, within-grade raises and promotions is more than offset by decreases resulting from a hiring freeze effective January 1985 and the proposed 5 percent Federal pay cut effective January 1986.

Low Income Home Energy Assistance

The Low Income Home Energy Assistance Program (LIHEAP) appropriation provides funds through grants to States and Indian tribes to enable them to provide assistance to low income households in meeting the costs of home energy. The FY 1986 budget request is for $2.1 billion for this purpose. This is a continuation of the level appropriated by Congress for the FY 1985 program. We believe this amount will provide a reasonable level of assistance to meet program needs while supporting the President's overall freeze of FY 1985 spending levels to reduce the deficit.

Oil Overcharge Collections

We are requesting an appropriation of $2.1 billion from general revenues. Legislation will be proposed, however, to authorize reimbursing the Treasury for part of the program's costs from receipts of oil overcharge collections. This refers to monies recovered by the U.S. Government which arise from petroleum pricing and allocation violations under the Emergency Petroleum Allocation Act of 1973. The Department of Energy will submit legislation proposing that these collections become revenues of the U.S. Treasury to be used to offset the costs of LIHEAP and two Department of Energy programs. Collections would be used in this way only in instances where the overcharged customer cannot be identified and repaid.

The budget assumes that the Government will receive collections in oil overcharge money totaling $1 billion for use in FY 1986. Of this amount, $809,476,000 would be authorized to offset costs of LIHEAP. These collections, when received, would offset the general fund appropriation for LIHEAP. The remainder of the estimated $1 billion in collections would be used for the Department of Energy's Weatherization Assistance Program and energy conservation grants to schools and hospitals. We would like to point

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out, however, that funding for LIHEAP is not contingent upon the recovery and availability of $1 billion in oil overcharge collections next year. We have requested an appropriation of $2.1 billion, and plan to make this amount available to grantees even if oil overcharge recoveries fall below our expectations.

Program Grants

We are requesting $2,097,840,000 in FY 1986 to provide grants to States, Indian tribes, and other jurisdictions to aid low income families through payments to eligible households and energy suppliers. States and Indian tribes use this assistance primarily for heating but may also use it for cooling and low cost weatherization. The FY 1986 request will allow continuation of program activities at the current level.

Federal Administration

The FY 1986 request includes $2,160,000 for funds to enable the Social Security Administration to administer the energy block grants for States, Indian tribes, and other jurisdictions. The FY 1986 request is for 32 full-time equivalents. Administrative activities include review of State and Indian tribe applications and amendments, issuance of grants, compliance and monitoring reviews, financial management functions, and preparation of the annual report to Congress. The $2,160,000 represents a $136,000 decrease from the FY 1985 level. This decrease is due primarily to reduced Federal staffing, the 5 percent pay reduction and other management efficiencies.

Limitation on Administrative Expenses

The Limitation on Administrative Expenses is a request for authority to spend up to $3,911,586,000 in FY 1986 from the trust funds for administrative expenses of the Social Security Administration. From this account we pay for administration of the old-age and survivors and disability insurance programs, Medicare work performed by SSA, and the construction needs of the Social Security trust fund programs. In addition, because for reasons of economy and efficiency SSA has integrated administration of both trust fund and some nontrust fund programs, the law authorizes payment of SSI and certain other

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nontrust fund administrative expenses from this account, with full reimbursement from general funds.

Of the new 1986 budget authority requested:

--$1.2 billion is for administering the old-age and survivors insurance program,

--$1.4 billion is for the disability insurance program,

--$137.4 million is for SSA's Medicare support functions,

--$909.7 million is for administering the SSI program,

--$67.3 million is for processing annual reports of earnings,

--Included in these activities is an estimated $182.9 million for automatic data processing and telecommunications activities,

--$36.9 million is for SSA's purchase contract payments and

--$175 million is for the contingency reserve.

Budget Emphases for FY 1985 and FY 1986

There are four general areas of emphasis in SSA's administrative budget for fiscal years 1985 and 1986.

1. Automatic Data Processing and Telecommunications

The FY 1986 request for new budget authority is $182.9 million. However, we estimate that we will obligate $264.9 million, the same level of obligations as in FY 1985. This level of obligations is more than double the FY 1984 level and is due to the carryover of unobligated funds from prior years. This funding will provide for SSA's continuing transition towards modernizing its systems hardware and software, as well as the Agency's ongoing systems costs. Included in the $264.9 million is $43.3 million for major telephone systems procurements and $221.5 million for ADP and telecommunications activities. Flexibility in implementation of the Systems Modernization Plan has been provided by special appropriations language first approved by this Committee for FY 1982 and requested again for FY 1986. This language allows SSA to use appropriations for ADP and telecommunications until they are expended. Further, the contingency reserve is available for automation expenses that exceed the budget estimates and that cannot be absorbed elsewhere.

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2. Disability Program Administration

SSA's budget assumes implementation of the Social Security Disability Benefits Reform Act of 1984, including resumption of periodic continuing disability reviews (CDR's) during FY 1985. In 1984 the Secretary announced a moratorium on periodic CDR's to allow time for SSA to address the problems which surfaced during implementation of the Disability Amendments of 1980 and because new legislation was pending. The moratorium was continued after the October 9, 1984, enactment of the Disability Benefits Reform Act of 1984, in order to give the Administration time to prepare new regulations and procedures to implement this Act. The resumption of the CDR process will require a great deal of planning and coordination.

It is difficult at the present time to predict the magnitude of the new workloads from the 1984 disability reform legislation. Therefore, we are requesting an increase for FY 1986 in the contingency reserve in the event that implementation requirements exceed budget estimates.

The budget request includes $741 million for the Disability State agencies, an increase of $55 million over the $686 million budgeted for FY 1985. Funds for the Disability State agencies account for 19 percent of the total amount for the Limitation account. The Disability State agency budget increases primarily because of the full year effect of resumption of CDR's and concomitant increased costs for purchase of medical evidence of record and consultative examinations. The State agencies will do most of the work related to the Disability Benefits Reform Act of 1984.

3. Taxation of Social Security Benefits

We are requesting $41.2 million in FY 1986 for the taxation of benefits provision of the Social Security Amendments of 1983. This is a decrease of $24.5 million from the $65.7 million estimated in the FY 1985 column of the FY 1986 budget. Under this provision, one-half of Social Security benefits received by taxpayers whose incomes exceed $25,000 for a single taxpayer, or $32,000 for married taxpayers filing jointly, have to be

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included in taxable income. Beginning in January 1985, SSA began providing annual statements of benefits paid to all beneficiaries. A substantial portion of the resource needs estimated for FY 1985 are for inquiry workloads in SSA field offices, teleservice centers, and processing centers. In FY 1986 we assume the one-time inquiry work will decline significantly.

4. Debt Management

The FY 1986 budget reflects continuing efforts to prevent overpayments and to collect overpayments that do occur. Collection processes provide due process rights to beneficiaries. As a result of SSA's efforts, collection of debt from all programs rose from $635 million in FY 1981 to more than $1.2 billion in FY 1984. In FY 1986 SSA expects to use about $205 million and 7,300 workyears in the social security and SSI programs to collect more than $1.3 billion--a net savings of over $1.1 billion. The administrative resources needed for debt collection in FY 1986 and FY 1985 are projected to decline by over $20 million and 1,000 workyears as compared to FY 1984 due to improved debt management practices, such as:

--an interim billing and follow-up system to manage debt owed by individuals no longer on the beneficiary rolls.

--a reduced level of overpayments due to a special mailing to old-age and survivors insurance beneficiaries asking them to update their earnings estimates, thus avoiding earnings overpayments, the number one cause of overpayments.

Workloads

SSA has a workload-based administrative budget. Some examples of principal workloads for FY 1986 are to:

--process about 3.3 million claims for retired workers, dependents and survivors; nearly 1.5 million claims from disabled workers, dependents and survivors; and about 1.1 million SSI claims.

--keep the beneficiary rolls current for 37.3 million persons under the Social Security cash benefit programs and for 4.1 million SSI recipients.

--complete 2.4 million redeterminations for SSI eligibility and payment amount.

--process 285 thousand hearings from claimants who are appealing decisions

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concerning their eligibility and benefits, primarily in the disability and SSI programs.

--post 221 million annual wage report items.

Workyears, Positions and Full-Time Equivalents

For this appropriation, SSA is requesting 81,255 workyears for FY 1986, a decrease of 2,308 workyears from FY 1985. We will obtain the reductions primarily from automation improvements and procedural changes. A few examples of these changes are:

--elimination of unproductive reviews and systems exceptions in the processing centers and the field offices.

--automation of the procedure used by field offices to furnish benefit payment information to State welfare agencies.

--increases in the amount of annual wage reports received on magnetic media rather than paper.

--expansion of the claims automated processing system to include cases formerly excluded from automated processing.

Other reasons for workyear decreases include:

--reduced requirements for taxation of benefits because second year inquiries are expected to be significantly lower.

--workload decreases, such as lower SSI claims workloads and lower student attendance workloads.

For the Limitation account we are asking for 69,541 full-time permanent authorized positions for FY 1986. This is 900 positions lower than the FY 1985 level. Overtime will be reduced by about 600 workyears in FY 1986 from the FY 1985 level, primarily because of the decrease in inquiries for taxation of benefits.

We are asking for 76,349 full-time equivalents (FTE's) in FY 1986, a decrease of 1,689 FTE's from FY 1985. This represents the estimated second-year savings from the SSA productivity improvement plan which we project will improve SSA's service to the public and increase productivity, chiefly through automation.

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Contingency Reserve

The FY 1986 request includes a contingency reserve of $175 million—an increase of $125 million over FY 1985. This increase will provide flexibility to deal with the many uncertainties during FY 1986 related to implementation of the disability reform legislation and management of the Agency's productivity improvement plan.

We are asking that the contingency reserve be increased rather than budgeting explicitly for workloads which may not materialize or which may be absorbed due to lower than budgeted workloads in other areas. This will ensure that adequate resources are available if needed for implementation of the Disability Benefits Reform Act of 1984 and for other purposes. For FY 1986, SSA proposes that the contingency reserve be made available, for the first time, for unpredictable costs related to the impact of automation on the SSA workforce.

FY 1985 Supplemental Request

We propose to transfer $10,000,000 from unobligated field office construction funds, which are no longer needed for that purpose, to increase funds available for telephone systems acquisitions. No new budget authority is requested

INTRODUCTORY REMARKS

Mrs. McSTEEN. Mr. Chairman, members of the committee, I am pleased to be here today to present the fiscal year 1986 appropriation requests of the Social Security Administration and the Office of Refugee Resettlement. These requests total $26.6 billion in budget authority, and they include payments to Social Security trust funds; special benefits for disabled coal miners; supplemental security income; assistance payments; low income home energy assistance; refugee and entrant assistance; and the limitation on administrative expenses account.

I want to mention some key administrative initiatives underway in SSA. Early in 1984, we stated four values which we believe are essential to manage the organization: to provide timely and accurate payment of benefits, to administer the program efficiently and effectively, to provide courteous and sensitive and dignified service to the people that we serve, and to strive to provide a better work environment for the people in our own offices.

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To support these goals, we have come up with eight objectives which we feel are essential to the completion of our mission. One is to effectively manage our workloads. Others are: to modernize the Social Security claims system; redesign the annual wage reporting system; manage the impact on SSA's personnel and organization as a result of automation; and to provide a reliable management information system. Also, we intend to improve our internal program instructions and information, and certainly we are challenged with effectively managing the disability program. Our eighth concern is issuing clear and concise notices to members of the public and our beneficiaries.

Central to many of these objectives is the continued progress of the SSA systems modernization plan. Largely as a result of systems and procedural changes, we have reduced large backlogs of work, and we are providing a faster response to the public.

Overall processing time for retirement and survivor claims declined to 22.8 days in 1984, an improvement of 5.5 days compared to the year before. Processing time for SSI aged claims declined 5 days. SSA processed the bulk of 130 million 1983 annual wage reports 6 weeks earlier than last year's processing time. We have speeded up the issuance of Social Security account number cards to about 11 days from what it used to be, 6 weeks.

In the Office of Disability Operations, we have reduced disability insurance claims backlogs by 23 percent. Certainly, our long-term productivity improvement plan is essential to ensuring that the next 6-year period, fiscal year 1985 through 1990, will show vast improvements in the way we do business and in our service to the public.

The only other issue I would like to mention is that of the Disability Benefits Reform Act of 1984, and certainly the implementation of that particular piece of legislation is going to be a great challenge to all of us. We feel that we are on our way to getting that implemented, and we will proceed very shortly to resume our continuing disability reviews.

Since we last met, as I indicated, there is a new director of the Office of Child Support Enforcement, and I would like Steve Ritchie to say a few words at this time.

PREPARED STATEMENT

Senator WEICKER. Your complete statement will be a part of the record.

[The statement follows:]

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STATEMENT OF R. STEVE RITCHIE

Mr. Chairman, members of the Subcommittee, I appreciate the opportunity to discuss the Child Support Enforcement program of the Department of Health and Human Services, and the budget we are proposing for FY 1986.

My recent appointment as Director of the Office of Child Support Enforcement, reporting directly to Secretary Heckler, reflects the special commitment of the Department to ensure that all parents provide their children with the support they deserve. I look forward to satisfying the mandate of Congress and the President to work with States and improve Child Support Enforcement.

Established in 1975 as part D of title IV of the Social Security Act (the Act), the Child Support Enforcement program helps to strengthen families and reduce welfare spending by placing the responsibility for supporting children where it belongs: on the parents. It is one of the few government programs that helps needy families while also saving tax dollars. Most of the child support collected through the CSE program for families receiving Aid to Families with Dependent Children (AFDC) has gone to the Federal and State governments to offset AFDC payments. However, the passage of the Deficit Reduction Act of 1984 requires, beginning in FY 1985, that the first $50 of each current child support collection be distributed directly to the family unit. As a result of this law, a smaller share of these collections now are returned to the Federal and State government.

For some families, the child support payments are high enough to enable them to leave the AFDC rolls. Support payments collected through the program for non-AFDC families go directly to the family to help them remain self-sufficient. In every step of the process, the rights of the father, mother, and children are preserved. The millions of dollars the Child Support Enforcement program collects each year represent a direct benefit to children and families as well as a direct saving for taxpayers.

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As most of you know, child support enforcement is a serious problem for many women and children in this country. Non-payment of child support has emerged as one of the most difficult social issues facing us. You have heard the sad statistics on this before. Half of the Nation's 15 million children who live in fatherless homes are poor. More than half of the women with support orders receive less than the full child support payment due them or nothing at all, and the average annual amount received in 1981 was $2,100.

The President and Congress have addressed this problem with the passage last summer of the Child Support Enforcement Amendments of 1984. The law that we now have in place will work hard for single-parent families: It will be responsive to their need.

The appropriation request for FY 1986 includes activities resulting from the Child Support Enforcement Amendments of 1984. This new law, P.L. 98-378, is the most significant legislation affecting the CSE program since the program's inception in 1975.

The new law has four major themes:

- o Child support services must be provided to all families that need them - welfare and non-welfare.
- o States are required to use proven enforcement techniques that work.
- o Federal financing and audits will be used to stimulate and improve program performance.
- o Interstate enforcement will be emphasized and improved.

These amendments will provide a more balanced approach to providing services to welfare and non-welfare families alike. Since the program was started, Congress intended that child support enforcement services would be available to both AFDC and non-AFDC families. P.L.98-378 amends the Social

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Security Act to further emphasize that assistance in obtaining child support must be available to all families who request child support enforcement services.

The FY 1986 budget request for Child Support Enforcement is $432,101,000. This is in addition to the $160,000,000 which Congress provided as an advance appropriation to fund first quarter State and Local administrative grants. At this time we are also requesting an advance appropriation of $170,750,000 to fund first quarter FY 1987 grants. The advance appropriation will provide funds in FY 1986 for issuing advance grants for the first quarter of FY 1987. Such a procedure enables States to continue program operations without interruption and to plan in advance.

State and Local Administrative Costs

The Child Support Enforcement Amendments require the States to use certain enforcement techniques that have been proven to work. Foremost among these is automatic, mandatory wage withholding when support payments are delinquent. Other procedures mandated by the new law are expedited judicial or administrative procedures for establishing and enforcing child support obligations, interception of State income tax refunds, liens against property, posting of securities or bonds, and reporting to consumer credit agencies. The new law goes on to redesign the financial incentive system to encourage States to operate more effective and efficient programs. The effectiveness and the level of collections of a State's child support enforcement program will determine the incentive payment the State will receive. These incentive payments, estimated at $150 million for FY 1986, are reflected as an offset to child support collections in the Assistance Payments Appropriation. We are requesting $558,929,000 of Federal funds to reimburse State and local administrative expenditures incurred in providing support enforcement services. A $13,071,000 decrease in budget authority is due to funds carrying over from FY 1985 into FY

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1986. On a comparable basis, the outlays for FY 1986 are $67 million higher than the corresponding amount for FY 1985.

Interstate Support Enforcement Project Grants

One chronic problem this nation has faced is one of enforcement of child support obligations between States. In order to correct this problem, the Child Support Enforcement Admendments authorizes $7 million in FY 1985, $12 million for FY 1986, and $15 million each fiscal year thereafter for demonstration projects to improve interstate enforcement. The purpose of this program is to investigate and demonstrate innovative methods of providing child support order enforcement across State lines.

Grants will be awarded in three funding cycles. It is anticipated that the first round of FY 1985 grant awards will be completed within the next month. For FY 1986, we are requesting $12 million for interstate support enforcement grants; the authorized level.

Research and Evaluation

We are requesting $500,000 for research and evaluation grants and contracts under section 1110 of the Social Security Act, the same as last year. These funds will be used to study ways to assess the ability of absent parents to pay child support, and for other purposes.

Federal Administrative Expenses

The FY 1986 request includes $20,672,000 in budget authority and 330 FTE's for Federal administration. This represents a decrease of $2,339,000 from the FY 1985 appropriation level. However, the outlays for FY 1986 are $1,163,000 less than the budget authority for FY 1985 as a result of the carryover into FY 1986 of savings realized in FY 1985. The overall

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decrease in FY 1986 is due primarily to savings from a hiring freeze and the proposed 5 percent Federal pay cut effective January 1986.

During FY 1986, our staff plans to aggressively pursue a program 1) to continue implementing the new legislation, 2) to build public awareness of the statutory changes, 3) to upgrade automatic data processing systems in order to handle the large increaase in workload resulting from the Law, and 4) to strengthen interstate enforcement.

The Office of Child Support Enforcement also performs reimbursable work for States. This reimbursable work requires 2 workyears and has an estimated cost of $59,000. This activity is authorized by the Kidnapping Prevention Act of 1980 to locate parents with custody of a child in violation of a court order.

Let me conclude by emphasizing the significant effort the Federal, State, and local governments are demonstrating in satisfying the challenge presented by the Child Support Enforcement Amendments of 1984. Through the continued cooperation of all the parties in implementing the new law, an improved, efficient, and effective Child Support Enforcement program can be obtained. I appreciate the opportunity to testify before the committee and will answer any questions you may have. Thank you.

BIOGRAPHY OF R. STEVE RITCHIE

Health and Human Services Secretary Margaret M. Heckler announced the appointment of R. Steve Ritchie as Director of the Office of Child Support Enforcement on February 14, 1985.

She said in a recent press release that his appointment reflects the special commitment her Department has to ensuring all parents provide their children with the support they deserve.

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Steve Ritchie has over 20 years experience in business and government as well as extensive U.S. and international travel. Before coming to Washington, he was owner and President of Steve Ritchie Associates, a Nevada based communications company with clients throughout the Nation. He is a 1964 graduate of the United States Air Force Academy where he was a starting halfback on the Falcons 1963 Gator Bowl Team.

In 1974, following a distinguished career in the United States Air Force as America's only MIG-21 Fighter Ace, Mr. Ritchie ran for Congress from his home State of North Carolina.

Ritchie brings to us as the newly appointed OCSE Director a commitment to keep moving vigorously toward our goal of assuring each child's right to parental support.

Along with the President and Secretary Heckler, he strongly supports the Child Support Enforcement Program and considers his appointment a unique challenge.

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CHILD SUPPORT ENFORCEMENT INTRODUCTORY REMARKS

Mr. RITCHIE. Mr. Chairman, members of the committee, we certainly appreciate this opportunity to discuss the Child Support Enforcement Program and the budget we are proposing for fiscal year 1986.

My recent appointment as Director of the Office of Child Support Enforcement, reporting directly to the Secretary, reflects the special commitment of the Department to do everything possible to ensure that parents provide their children with the support they need and deserve. We certainly look forward to satisfying the mandate of the Congress and the President to work with the States to improve child support enforcement.

As you are well aware, nonpayment of child support has emerged as one of the most difficult issues of the day. Of the 15 million children who live in single-parent homes, the vast majority—some 90 percent—are headed by women. Far too often, the absent parent is not fulfilling his or her legal obligation to pay support. In fact, in 1981, more than one-half of all mothers with support orders received less than the full amounts or no payment at all. The average annual support amount received for both welfare and nonwelfare families was only $2,100.

Another indicator of the extent of the problem is that two-thirds of the children born this year will, at some time during their lifetime, experience the child support system, either as a child of a family receiving support or as a parent that pays or receives support.

Without child support many children and their custodial parents are driven to public assistance. The President and the Congress have addressed the problem with the enactment of the Child Support Enforcement Amendments of 1984. The new law will be more responsive to the needs of single-parent families.

The appropriation request for fiscal year 1986 includes many activities resulting from the 1984 amendments. This is the most significant legislation affecting child support enforcement since the program's inception in 1975.

The budget request for fiscal year 1986 is $432 million. This is in addition to the $160 million which Congress provided in 1985 as an advance appropriation to fund the first quarter of 1986. We are also requesting an advance appropriation of $170.75 million to fund the first quarter of fiscal year 1987. This procedure enables the States to continue program operations without interruption.

During fiscal year 1986, we plan to work intently in four broad areas: one, to vigorously continue to implement the new legislation; two, to build public awareness of the statutory changes; three, to upgrade automated data processing systems in order to improve the current management of the program and to handle the increased workload resulting from the new law; and four, to strengthen the interstate enforcement system.

Mr. Chairman, in closing, we wish to emphasize the significant effort the Federal, State, and local governments are demonstrating in working to satisfy the challenge presented by the Child Support Enforcement Amendments of 1984.

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Through the continued cooperation of all parties in implementing the new law, we believe an improved, more efficient and more effective Child Support Enforcement Program can be achieved. Thank you.

PROPOSED EMPLOYMENT REDUCTIONS

Senator WEICKER. Thank you. You are proposing to cut 17,000 Social Security staff, through attrition, over 6 years. This includes a reduction of 3,600 full-time equivalent positions by the end of fiscal 1986.

Could the Social Security Administration really absorb a cut in its staffing of this magnitude without major disruptions in its operations and service to the public?

Mrs. MCSTEEN. We recognize this as a tremendous challenge to the organization. We have never before faced this kind of a reduction. We do believe that the time has come that we need to take a look at how we deliver services and how we can continue to deliver those services.

Our plan involves a very careful assessment of what we would be doing over the next 6 years in order to assure that the 17,000-reduction plan works smoothly, and we believe that we can accommodate that through attrition—our attrition normally in a given year is around 4,000 full-time permanents and about 1,000 part-time permanents—recognizing, of course, that attrition is not the only way to do that, that attrition will not solve all the problems, but, indeed, it is a giant step forward in helping us meet these goals.

We plan to improve our productivity. Certainly, we know through the systems modernization plan, we will be able to save enormous amounts of time as the years proceed, through the claims modernization of title II and, subsequently, title XVI. We intend to make this reduction without a reduction in force, and we have been assured by the Secretary and others that she would support us in this endeavor.

We recognize that it perhaps is Social Security's greatest management challenge in its history. It is going to require recognizing where jobs are being eliminated due to automation, and it will require us to retrain those individuals. The greatest problem will be the imbalance of staffing, and it, undoubtedly, will cause us to offer employees opportunities in other locations and, if necessary, to relocate individuals.

ORIGIN OF EMPLOYMENT REDUCTION PLAN

Senator WEICKER. Would you describe for the committee what the origin of the proposal is and how the cuts will be taken?

Mrs. MCSTEEN. When we submitted our budget request in mid-1984, we did so in the same manner that we normally have done, looking into the future about 2 years. Later we were asked to consider a 19,000 reduction in full-time equivalents over a 3-year period, and we felt we could not continue to deliver the services that we deliver if the cut were in that period of time and to that degree.

Subsequently, OMB agreed with the Department of Health and Human Services that SSA would go with a reduction of 17,000 FTE's, downscaling over a 6-year period through 1990. We plan year by year

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to take this into account. We would have a change in 1985 of a 2.4-percent decrease in FTE's; 4 percent in 1987; and 4.6 in 1990, to give you a range.

We intend to reduce staff positions in regional offices and headquarters by 15 percent. We intend to expand the district office authorization for final processing of claims, and we intend to streamline our delivery process. Those are some of the ways that we intend to move ahead with it.

SERVICE DELIVERY

Senator WEICKER. Last December, you wrote a memorandum to the Assistant Secretary for Management and Budget concerning staff reductions being planned during the fiscal 1986–90 time period. The memorandum in part stated:

> Efforts will be made through a formal review process of the existing field offices to streamline service delivery. While this could result in eliminating 100 to 200 permanent facilities, we will strive to accomplish the objectives without diminution of services to the public.

So my questions are as follows: How can you close the offices, particularly in rural areas, without hurting services, especially to the disabled and the poor? And when will you know exactly how many offices would have to be closed as part of your planned 25-percent nationwide staffing cut?

Mrs. MCSTEEN. Through the years for several decades, Social Security has maintained a review of all offices and services delivered to ensure that our offices are properly staffed, to ensure that new offices are opened or offices downscaled if the workload calls for it.

In fiscal year 1984, we made the decision to close 12 offices, and to downsize 9 offices; we also decided to upgrade 4 offices. My point is, that through the years, we have looked carefully at the service we deliver and the size of our offices. We recognize that there are characteristics in certain populations, whether served by urban or rural offices, that require the continuation of the present service delivery approach.

The only thing that has changed in this particular procedure is that we have formalized and asked our regional commissioners to have a plan in the next 3 years to carefully look at all offices in their region to ensure that they are properly staffed, and that we can deliver services in the best possible way. We are not saying that we will close any office. There is no plan; there is no named office that will be closed. It will be a pursuit of the factors that determine the need for these offices, just as we have done in the past.

We opened a number of offices, as you recall, in the 1970's, in order to accommodate the new SSI workloads. Many of our workloads have diminished, and we find that population shifts have caused us to downscale or increase our service in certain locations.

We also find that many people want to use the telephone and, thus, we have created teleservice centers throughout the country to be more responsive to the needs of the people who wish to do business by telephone.

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BUDGET FOR SYSTEMS MODERNIZATION

Senator WEICKER. What is your 5-year plan vis-a-vis computers and, specifically, is there an increase in this year's budget for modernization of the computerization system?

Mrs. MCSTEEN. Our systems modernization is coming along well. We feel that we have made giant strides in our accomplishments, but have yet a long way to go. Certainly, the initial hardware acquisition, that first period, has been completed successfully. We are now in a transition period, one of the more difficult periods because of the conversion of the software.

We originally projected the entire systems modernization plan over the first 5-year period to be about $479 million. At that time, we were not including the management information system, which I feel is essential to the operation of any large organization, and that will be included in our plans.

Our accomplishments are varied in the systems modernization plan. We have slipped in some respects, but we are ahead of schedule in others. We, this month, have opened two model offices, meaning that they are equipped with terminals. This is our test office to ensure that data entered into our central computer system will be maintained and that we can extract data from a central base and, therefore, process our claims in a very modern, up-to-date manner, more accurately and much more quickly.

Our title II claims modernization plan will expand to two offices in each of the regions in the next year and a half, and then we will move across the country in 1987, intending to have all of our offices upgraded at that time.

Senator WEICKER. Dollar-wise, again, what is this budget compared to last year's? Increase in funds? Decrease in that area?

Mrs. MCSTEEN. We are able to carry over some of the budget authority, so the fiscal year 1986 request for no-year funds for ADP/telecommunications is $27.2 million lower than in fiscal year 1985. Our total resources in terms of obligations in 1985–86 are about double what we used for the past 2 years; and in terms of budget authority we estimate for 1985, $210 million, and in fiscal 1986, $183 million.

IMPROVEMENTS DUE TO SYSTEMS MODERNIZATION

Senator WEICKER. My last question, after all this, before I yield to my colleagues, as I see it, you are having personnel reductions; we have some carryover funds, but, nevertheless, the request insofar as computerization is concerned is actually static or actually down, and yet the statistics that I receive relative to the population which is going to be 65 years of age or over, or 85 years of age or over, in another particular instance, the statistics I receive are staggering insofar as their increase is concerned. Maybe there is something going on there, if you don't do it with people, and you don't do it with machines, what are you going to do it with?

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Mrs. McSTEEN. We feel our systems modernization is progressing as scheduled, and I think the fact that the cost-of-living allowance was processed in 2 days instead of 2 weeks, that is a giant step forward. Some 80 million title II master beneficiary records are online for our district offices today, that saves time. We have 370 million Social Security records online this month. Postentitlement actions that give us a lot of problems are processed 5 days a week instead of 2 or 3 days a week as in the past.

Senator WEICKER. Let me say one thing right now, I don't doubt for 1 minute these things are as you say they are, but they obviously relate to investments that were made several years back. My concern with so many of these budget cuts proposed, they look great as far as the bottom line on paper this year in the budget, but in instance after instance, my concern, it should be properly my concern, as it is my colleagues', will be the out-year costs of either freezes or cuts now.

I might not be around here, but I should at least have the responsibility of knowing what is going to happen by virtue of my action today, and that was the nature of my question to you.

I know the statistics, as I said, the population you are going to serve, and it is just going to be monolithic in terms of increase over today's population, yet the budget that sits before me seems to clearly call for cutbacks as far as personnel is concerned.

Insofar as the computerization program, I don't see anything here that would take up the slack of the personnel.

Mrs. McSTEEN. We really do feel that because of our carryover authority, we have sufficient moneys to fund all that we can handle in the systems area in processing improvements in the next 5 years. And I think as long as our schedules are met and we are able to move ahead with our modernization, that we will be able to serve the public.

Senator WEICKER. Senator Chiles.

EFFECT OF EMPLOYMENT REDUCTIONS ON ERROR RATES

Senator CHILES. Thank you, Mr. Chairman. The President's budget reduces 17,000 full-time equivalent positions over a 6-year period, and this results in substantial dollar savings in the amount budgeted for administrative costs. Your memo of December 11 to the Assistant Secretary for Management and Budget indicates there will be a need for substantial shifting of employees from one job to another in order to carry out your personnel reductions. That could easily lead to an increase in the overpayment error rate.

Moreover, the same memo describes your intent to shift some final claims payment from the six program service centers back to the district offices. The memo states as a result of this change, "the payment error rate could be affected since the cases currently not under district office final approval are the more complex and error-prone."

If your proposed reductions in personnel were to increase the overpayment error rate, the budgetary savings you are projecting might be wiped out and perhaps turned into a net cost to the Federal Government.

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For example, if the overpayment error rate were to increase from 0.4 percent, which it is today, to 1 percent, the Federal Government's cost would increase by $1 billion next year.

How much of an increase in cost arising from increased error rates has been incorporated into the President's budget for fiscal year 1986 through 1990?

Mrs. McSTEEN. Senator Chiles, we don't believe that our overpayments and our error rates will escalate. We have launched a debt-prevention program, and we are trying very hard to ensure that we prevent debts before they happen and that our accuracy rate is improved at the same time.

With the delegation of the final adjudication from the program service centers to the field offices, and we have looked at it very carefully over a number of years, and with the capacity that we have in the field offices now, we find that the accuracy rate is equal, if not better, than the accuracy rate in the program service centers. It is a means of ensuring a quicker payment for the individuals who file claims. So I really don't worry about that delegation or about the quality of payment.

Senator CHILES. Your answer then is you have not programmed in additional, for there to be any increase in the error rate, zero dollars for increase in the error rate?

Mrs. McSTEEN. We do not expect an increase in the error rate.

Senator CHILES. Isn't that irresponsible budgeting on your part to provide no room for an increase in overpayment when you acknowledge in your own memo that increases are likely to occur?

Mrs. McSTEEN. Well, I'm not sure what memo you have, but certainly I feel through our greater automation and through putting the computations on line, we have been eliminating manual computation and that we will make less errors. I think that would stand on its own.

Senator CHILES. Do you want to fill into this answer? You look nervous there.

Mr. SABATINI. You are referring to a memo dated December 11. The memorandum the Commissioner signed makes no reference to an anticipated increase in programmatic errors. As the Commissioner said, our data show that by moving this final adjudication authority that error rates will be at least stable or they might improve because there is less manual handling.

DISTRICT OFFICE FINAL AUTHORIZATION

Senator CHILES. I am looking at this district office final authorization.

Loss of a significant number of claims authorizers in the processing center raises several key concerns over impact. First, the payment error could be affected since the cases currently not under DOFA are the more complex and error-prone. Second, a large proportion of the displaced CA's will have to be reassigned to operation jobs in the field office or in headquarters.

Another possibility to be considered is to train the CA's on disability evaluation so they could be utilized in the event of DDS Federalization. This would be not only all the costs and labor problems associated with this, but also considerable training efforts.

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Mr. SABATINI. I don't think that is our memo, sir. Could we see it?

Mrs. MCSTEEN. There has always been concern about moving the workload from the program service centers to the field offices because of the workloads and to say if that workload is transferred, we may have more authorizers than we need to process that workload. There is nothing unusual about that.

Senator WEICKER. Come on, you guys know about this memorandum.

Mr. SABATINI. It is not ours. Some of the attachments were not part of the memorandum package which the Commissioner signed.

Senator WEICKER. I know, but you have seen this thing before. I gather that you have the authenticity of it in your own ranks.

Mr. SABATINI. This [holding up the memorandum and the first two pages of attachments] is what was sent by us. That [holding up the other attachments] is part of an earlier staff critique of the reduction plan.

Senator CHILES. Do you know who prepared it?

Mr. SABATINI. No; I'm not sure.

Senator CHILES. It looks like it is prepared on the same typewriter to me. [Laughter.]

Mrs. MCSTEEN. I think that some clarification is needed here, and I would like to supply that for the record.

[The information follows:]

CLARIFICATION REGARDING THE ACTING COMMISSIONER'S DECEMBER 11, 1984, MEMORANDUM TO THE ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET

Unfortunately, the package the committee has in its possession creates the misleading impression that there is one document, signed by me and representing my point of view. Since I first saw this document, at my appearance before the Senate Appropriations subcommittee, I have looked into its origins. I found that two separate and distinct documents are involved, prepared for different purposes and at different points in time. Both documents reflect an earlier reduction of about 19,000 full-time equivalents [FTE's]. Neither reflects the current FTE plan, details of which were provided to Ways and Means Committee staff and Appropriations Committees staff in February.

Materials in the committee's possession are a combination of: (1) a two page briefing document prepared for the Secretary at the request of the Assistant Secretary for Management and Budget and forwarded to him with a one-page transmittal memorandum dated December 11, 1984, which I signed; and (2) excerpts from an earlier lower-level staff paper.

The committee's concerns about these documents focus on a perceived threat to service delivery and payment accuracy. The Secretary and I are committed to maintaining or improving payment accuracy and to assuring that service is not threatened by the productivity improvement plan. For example, in her testimony before the House Appropriations subcommittee, Secretary Heckler advised the Congress that she has:

"* * * secured an absolute guarantee that if there is any glitch in the introduction or phasing in of the new modernization equipment, there will not be a phasing out of personnel. The equipment must be in place and the system working before the personnel are phased out."

In summary, the plan is subject to change based on actual agency workloads, achievement of automation goals and other factors.

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MEMORANDUM

Senator WEICKER. A little original thinking within the administration, even though it might be contrary to OMB, it is not a bad thing to have, a little of your own thinking, critiquing, pointing out some of the problems that might arise. There is no reason why you shouldn't be doing that in the administration.

Senator CHILES. Can I have the bogus document back? [Laughter.] Mr. Chairman, I don't understand this, but I see the first three pages of the memo and cover saying,

In accordance with our conversation, attached is a condensed version of the plan for FTE reduction at SSA during the fiscal year 1986–90 time period.

Then I see the next pages, explanation of the chart and implementation plans.

Mr. SABATINI. Yes, sir; this is our memo, sir.

Senator CHILES. So the explanation, the back page——

Mr. SABATINI [interposing]. The back pages were not attached to our December 11 memorandum. I disagree with the statement on final adjudication because our data show the error rate remains the same. As a matter of fact, there is some indication it may improve by moving that final authority to the district office because there is less manual handling of the case, which causes errors.

Mrs. MCSTEEN. We have tested that procedure, Senator, and we will be glad to enter into the record what that shows for the final authorization in the program service centers versus the district and branch offices.

[The information follows:]

FINAL AUTHORIZATION IN PROGRAM SERVICE CENTERS VS. FINAL AUTHORIZATION IN THE DISTRICT OFFICES

A great majority of the initial Social Security claims applications that are approved for payment are authorized for payment by district offices. These cases are referred to as district office final authorization cases or DOFA cases. The remaining applications for Social Security benefits are sent to the program service centers for final authorization because these cases involve more complex eligibility issues and are more likely to require additional development before eligibility and benefit payment amount can be established.

In recent years SSA has increased the types of cases that district offices can authorize for payment under DOFA. Most recently we completed the second phase of this expansion of DOFA cases, to the point that approximately 89 percent of initial cases are authorized in the district offices. Based upon our experience, when SSA transferred responsibility for final authorization from the program service centers to the district offices, we noted no increase in the payment error rate. In fact, the phase II expansion of DOFA resulted in a slight increase in payment accuracy from 95 percent payment accuracy in the program service centers to 95.2 percent payment accuracy in the district offices for the type of cases transferred under phase II.

FINAL AUTHORIZATION

Senator CHILES. Let me ask you whether you agree or disagree with this. Is this totally fallacious reasoning and, if so, I would like to know who wrote it. When it is talking about the district office final authorization:

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This will mean not only all the costs and labor relations problems associated with physical relocation of personnel, but also a considerable training effort and attendant loss of productivity to get the CA's prepared for their new positions. Third, the loss of the CA positions will have serious repercussions on the remaining structure. The modular structure and the numbers and grade levels of the supervisory and management personnel are all keyed to the CA position. A large reduction in the number of CA's will mean extensive staffing, classifications, and labor relations problems for the remaining structure as well.

Mrs. McSTEEN. I would say that kind of rationale is what we have heard in the past from the people in the program service centers who are concerned about their authorizers, their grade structure and their workloads, and that sounds to me like one side of a discussion regarding where the claims are to be adjudicated and what impact it has. We have been through this before. Certainly there are pros and cons of maintaining workloads in one place or another, but our studies have revealed that it is done equally as well in the field offices and that is why we are now sending these claims, additional ones, to the field office.

We have been assured that accuracy will be maintained. This has been an issue for years.

CONTRACTING OUT

Senator CHILES. It is our understanding you have already begun the A–76 process for contracting out certain procedures now performed by the three data operations centers around the country. The A–76 process includes contracting out the data entry activities for the annual wage reporting process. This bogus memo states that:

It was determined several years ago that the entire annual wage reporting process is an inherent Government function which, therefore, will not be contracted out. The then-Commissioner of Internal Revenue Service participated in this decision which was concurred in by the Office of the General Counsel. If we are to contract out the keying function associated with the annual wage reporting process, we will need relief from that decision.

Is that something that you will need relief from, or do you not care about that previous decision?

Mr. SABATINI. Senator, that December 11 document was based on, as the Commissioner stated, the original OMB passback that called for a 19,000 reduction. In the final plan, the 17,000 reduction over a 6-year period, one of the things we have dropped is the assumption of contracting out those functions. What we are saying and what the experience in the Government shows is that if you follow the A–76 process, which initially involves a management review of the process that you are looking at, and you make changes to make that the most efficient process possible, and then finally you go out for bids, in most cases you do not contract the function out. But what you realize is approximately a 25-percent savings as a result of the efficiencies introduced into the process from the management review.

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The plan that we have laid out calling for a reduction of 17,000 as opposed to 19,000 only anticipates those savings that will come about as a result of the efficiencies introduced, not the contracting out of the entire function.

Senator CHILES. But you have begun A–76 review, the management review, but you don't intend to go through with it?

Mr. SABATINI. We want to do the review to make the process the most efficient process we could possibly have and get the savings that would be derived from that, and that is projected in the budget.

Senator CHILES. But you don't anticipate the annual wage reporting process being contracted out so you would not need relief from any——

Mr. SABATINI [interposing]. No.

EMPLOYMENT REDUCTIONS

Senator CHILES. I know the Senator from West Virginia has some questions, the minority leader. The President has submitted a budget request on that 17,000, roughly 21 percent of the Social Security population. I assume Florida would lose at least several hundred workers in Social Security offices as a result of that proposal. Can you give me any idea what Florida's losses will be?

Mrs. MCSTEEN. No; we do not know where there will be decreases in the workloads, nor have we broken it down to small offices. The major changes will come about through the systems modernization, when we have our system in place in all the offices in 1987.

PILOT TESTING OF NEW PROCESS

Senator CHILES. I guess the biggest problem I have, Mr. Chairman, is trying to determine how we understand we can save 17,000 without affecting services, and we are just now starting to pilot test this. You haven't pilot tested it before. It seems to me that is sort of a backward process of how you go about to pilot test something, find out whether we can do it, then build up our numbers from there.

It looks to me like the numbers came down, save this much and then you are rationalizing now that we can do all this without affecting the service.

Mrs. MCSTEEN. No; the systems modernization plan will extend over a number of years, and we have recognized all along that it is going to be a continual process. We have only budgeted in the past, as you know, for the current year and the subsequent year. Now we have more long-term projections. We can't expect them all to occur in the 1 year——

Senator CHILES [interposing]. Are you not just starting pilot testing in York, PA, and Baltimore right now?

Mrs. MCSTEEN. Yes; because that is the time when we were supposed to begin. It was not scheduled previously because we were not ready to begin.

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Senator CHILES. But all the savings are based on things that have not been tested.

Mrs. MCSTEEN. No; we have tested. We have had a model office in our headquarters to work out all the bugs. What I am saying about our pilot offices is that we are opening them to the public. We have tested. We have tested in our model office what is to come up on the screens in the pilot offices.

Senator CHILES. You don't call that model office equivalent to pilot testing.

Mrs. MCSTEEN. Yes, I do. We needed the model before we could go live in the pilots.

Senator CHILES. You do. I yield.

CLOSING FIELD OFFICES

Senator BYRD. Mr. Chairman, you and Senator Chiles have expressed the same concerns that I have, and you have covered the questions in most part that I was going to ask.

Do I understand you to say you don't know how many field offices will be closed or what field offices will be closed?

Mrs. MCSTEEN. You are correct. We do not know which ones because it would be absurd to say we are going to close *x* number of offices blindly.

We are going to look, as we have in the past, at why we need offices and what kind of services we need in those offices, and that differs in different parts of the country.

Senator BYRD. Do you imply that when you reduce the number of employees by 17,000, you don't know how many field offices will be closed or whether any will be closed?

Mrs. MCSTEEN. That is right because when we downscale an office, we may find that through the systems modernization or through improvement in our procedures, we do not need 100 people in that office but maybe we need 75 people in the office. That is the kind of adjustment that we have always made in the way we do business.

Senator BYRD. Senator Chiles, is this the bogus——

Senator CHILES [interposing]. No; that is the good part. They acknowledge that. [Laughter.]

Senator BYRD. I think it has gone from a bogus memo now to a mystery memo. What do you say about the Select Committee on Aging projection, the closing of some 280 or 281 field offices? What do you say about that?

Mrs. MCSTEEN. Well, there have been so many projections of how many offices we are going to close. Some people have said we are going to close 700. The Grace Commission report suggested that we close all but 500 offices. We have 1,318 district and branch offices, and the Grace Commission report suggested that we didn't need more than 500. So almost any number you could pick, someone was saying this is what we are going to close. I maintain that we have no plan to close any particular given office at any given time.

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Senator CHILES. But you say 100 to 200 yourself.

Mrs. MCSTEEN. This was a long-range projection of what could be the potential result of the service delivery assessment. Based on the reviews, it may be necessary to do that. The paper you are quoting from reflected the 19,000 reduction and not the 17,000 figure.

Senator CHILES. You projected 2,000, in the 19,000 figure, you projected 2,000 bodies for streamlining.

Mrs. MCSTEEN. That is right, 2,000 full-time equivalents.

Senator CHILES. The next paragraph you have on streamlining, it says you will have to close 100 to 200 offices. It seems like to me, if you are going to get that 2,000 bodies or that 2,000 factored down to 17,000 as opposed to 19,000, obviously you are going to have to close 100 to 200 offices at least.

Mrs. MCSTEEN. We are talking about a 6-year period. As I mentioned, in fiscal year 1984 we decided on 12 closings of offices, and 9 downsizings and 4 upgrades. So we just simply have to look in the next 3 years at all of our offices to determine the needs.

Senator CHILES. But you were not under a mandate to reduce 17,000 employees the last time where you had that upgrading and downgrading.

Mrs. MCSTEEN. Well, I don't think that has anything to do with the 17,000. If the population shifts and you have a new community, we are going to serve that community, and that may mean the opening of a contact station or resident station, shifting some of our people from one area to another.

IMPACT ON SERVICE

Senator BYRD. I cannot understand how you propose to reduce the number of employees by 17,000 without first doing an impact study. Have you done any impact study on the offices to see what the impact would be?

Mrs. MCSTEEN. The impact study has to be done at headquarters and in the program service centers as well as the field offices, because we do have around 15,000 people in headquarters and 12,000 in the program service centers, as you know. We have had, as one of our objectives for this past year, a study of workloads to determine where those workloads are, where they need to be shifted and who can handle those workloads.

Senator BYRD. What does that show with respect to West Virginia?

Mrs. MCSTEEN. Well, sir, we do not have any of the FTE's or the offices by State broken down. We are still talking about a 6-year period, and we have just begun the service delivery review. I think it is impossible to project what is going to happen in any given State, except that we intend to maintain the service that we have always maintained.

Senator BYRD. We are aware what the impact will be in services in other States. You are going to have an 11-percent increase in the number of individuals who will be eligible for Social Security.

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Mrs. McSTEEN. Yes; there will be an increase in the Social Security beneficiary population.

Senator BYRD. So you have trains running on two different tracks and you are contemplating a reduction in personnel by 17,000 over 6 years, and you say it may not result in any closings; you have done no impact studies to determine what the effect would be on offices. I can't understand how you arrive at the answer before you investigated the impact of these offices and have some indication of where the offices will be.

Mrs. McSTEEN. We do have a formal plan for looking at all the offices in this country during the next 3 years, and it will be that process of looking at all the offices to determine what the population is, whether it is an aged population, whether it is a rural or urban population, whether there are large employers there, how much people use the telephone, what kind of service——

Senator BYRD [interposing]. Hadn't you better do this before you start cutting back on all these employees?

Mrs. McSTEEN. Well, we have not cut back on these employees yet.

Senator BYRD. But you are going to over the next 6 years.

Mrs. McSTEEN. If we manage well and if our system proceeds with modernization efforts as we predict, if the dedication of the employees remains and we are willing to try to do things faster and smarter and work harder, then we can do it.

It is a management challenge and we are not excited about the prospects of taking it on, but we feel that it is our responsibility to be prudent in our planning and to ensure that we deliver the services and that we are responsive to the Congress in every way. If we find that we can't do it and we have glitches and we don't move along in our systems modernization, we will come to you and tell you, and that is part of the agreement with the Secretary and with OMB.

FACTORS CONSIDERED IN CLOSING OFFICES

Senator BYRD. In West Virginia, we have taken away their bus service. I voted against bus deregulation, Mr. Chairman, so we have taken that away. We have taken away the airlines. I voted for airline deregulation. I wish I could have an opportunity to vote again. Just as soon as we did that, the big airlines began pulling out, charging higher fees, higher rates. You can go to Europe for just a little more than it takes you to go to Charleston and back from Washington. So we have airline deregulation. We have bus deregulation. Now they are going to take away Amtrak. How are these people going to travel? How are they going to get to the Social Security offices? Do you not intend to have some kind of study which would indicate where the closest Social Security office would be once you closed down, let's say 17 offices in West Virginia? I would like to know what the distances are to the next Social Security office.

Mrs. McSTEEN. Well, you are absolutely right. That is a part of the study. Distances, of course, are considered and the transportation is considered, and if we need more telephone lines and we need toll-free

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calls, we may need to revert to that. I appreciate your concern. We are as concerned about how the people get to our offices. And all I can do is again to reassure you that, as in the past, we have delivered services and we have been responsive to you and others, and we will continue to do so. If we intend to close an office, our procedure in the past has been to go to the community and explain to the leaders in the community and to the congressional offices what is going on. Generally when we have had a closing of an office there is an agreement that it is no longer needed in that particular area.

Senator BYRD. For the record then, you are not prepared to state whether or not there will be any closings of offices in West Virginia?

Mrs. MCSTEEN. You are right, sir.

Senator BYRD. Mr. Chairman, I think we ought to try to find out what the impact will be on offices in the various—I can't conceive how you can reduce the number of employees by 17,000 without knowing or having a pretty good idea where the offices are located that would most likely be impacted by such reduction in force.

Mrs. MCSTEEN. Of course, the 17,000 will not come exclusively from the field offices, as you know. And we project attrition at around 4,000 a year for full-time permanent employees and about 1,000 a year for part-time permanents; 5,000 normally attrition out of the organization in a year. That doesn't solve the problem, but it does tell you that we are accustomed to employment reductions in recent years.

Senator BYRD. What are the factors that will determine the need for a given office?

Mrs. MCSTEEN. I am not certain that I can recite each one of them. It is a very detailed analysis, but it does include the age of the population, the density of the population, the literacy of the population, the number of large employers and self-employed persons, a whole range of factors that one would assume had to be considered when you are opening a Social Security office.

Senator Weicker. For example, being the minority leader and a member of this committee. [Laughter.]

Senator BYRD. Would you submit for the record——

Mrs. MCSTEEN [interposing]. I didn't say that. [Laughter.]

Senator BYRD. I don't particularly blame you. I just think it is unrealistic to move in this direction to say we are going to have such and such a reduction and the number of employees amounts to about 21 percent. We are not going to impair the services of these offices—as a matter of fact, the services will probably be better. I would like to ask you to submit for the record the factors by which you will be guided in the closing of offices.

Mrs. MCSTEEN. Fine.

[The information follows:]

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Service Delivery Project—Information

May 8, 1985

Acting Commissioner of Social Security

Service Delivery Project--INFORMATION

See Below

Although there has been some controversy regarding our study of service delivery, I believe that you will agree that this activity reflects a sound management practice that will insure the best delivery of our services in the future. The continuance of our management stewardship fully supports and affirms two of our stated SSA values--effective and efficient administration of the program, and courteous, sensitive, and dignified service to the public.

SSA has had Administrative Directives System (ADS) Guide procedures in place for many years to address the issue of field office location and modification. In our efforts to improve our delivery of service, I believe it is necessary to update these procedures. Thus, we have been developing a methodology for national service area reviews. A work group of five regional representatives met in Baltimore in January and combined the best elements of several previously proposed review methodologies. The resulting methodology has been reviewed by the Regional Commissioners and will form the basis for our ongoing field service delivery evaluations. I want you to know that I am in full support of the service delivery project's objectives and the final methodology. I believe that the document contains a clear set of workable and sufficiently flexible procedures.

While the service delivery project is an SSA-wide endeavor, I have asked the Acting Deputy Commissioner for Management and Assessment to take the oversight lead. The Deputy Commissioner for Operations will have primary responsibility for the conduct of the reviews. Because the project encompasses a wide range of issues, the Acting Deputy Commissioner for Programs and Policy and the Acting Deputy Commissioner for Systems will also play major roles as the project evolves. This activity represents a formally stated position as it relates to our stewardship responsibility to provide cost-effective quality service in the present and anticipated future environment. Together we can continue to demonstrate our commitment to being an exemplary employer by approaching this effort in a reasonable, flexible, and concerned manner. Your leadership and recognition of the value of SSA staffs will enable us to find the solutions to our current challenges.

Martha A. McSteen

Addressees:
Acting Deputy Commissioner, Management and Assessment
Deputy Commissioner, Operations
Acting Deputy Commissioner, Programs and Policy
Acting Deputy Commissioner, Systems
All Regional Commissioners, SSA

Service Delivery Review Methodology

INTRODUCTION

SSA principles have remained essentially unchanged over the years as demonstrated by the Acting Commissioner's Bulletin on SSA values. We have always believed that we have a responsibility to provide correct information in a courteous manner to all persons who call or come to our offices.

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The concept of "service to the public" is complex because our public includes the "taxpayer" in a broad sense and all beneficiaries and recipients.

SSA has always used certain criteria to determine how to deliver service. These criteria have included population numbers and population characteristics, numbers of Social Security beneficiaries and SSI recipients in an area, accessibility of facilities and other pertinent factors. Between 1936 and 1960, offices were established based on population centers and expected workloads. There was a needed expansion of field facilities in the 1960's and early 1970's to reach out to minority and socioeconomically deprived segments of our society. Through the years we have constantly looked at our service delivery needs. It is obvious that this activity needs to be continued in an organized manner. Current and future lifestyles, technology, population shifts, geographical changes and organizational resources must be considered as we look at the delivery of our services.

The review of facilities has been an ongoing effort, although it has not been uniform SSA-wide. Since January 1981, reduced workloads, shifts in populations, management and other considerations, have resulted in the following changes: (1) the closing of 1 district office; the closing of 17 branch offices and 2 resident stations; the conversion of 7 district offices to branch offices, 26 branch offices to resident stations, 1 branch office to a contact station and 5 resident stations to contact stations; also (2) the opening of 1 district office and 2 branch offices; the conversion of 4 contact stations to resident stations, and 3 resident stations to branch offices. During the period September 1982 to December 1984, 605 contact stations were closed and the frequency of visits reduced in many others. These actions were taken because they enabled us to improve the efficient delivery of our services.

The service delivery project fully supports two important SSA values, to administer the program efficiently and effectively and to provide courteous, sensitive and dignified service to the public. We will continue to look carefully at the nature of the services provided by SSA. The establishment of uniform national guidelines for determining necessary changes and developing plans for the future will ensure our success. Obviously, no single concept of service will suffice for all times and all places, but implementation of an Agency-wide Service Delivery Plan will be a positive step in ensuring that SSA provides cost-effective service while assuring acceptable access to these services.

I. Methodology

In applying a reasonable, systematic study methodology for a comprehensive review of how best to utilize field resources to serve the public, we have always taken into account service needs and the costs for providing these services using a variety of approaches. The methodology for these reviews has as an objective the application of uniform procedures to look at service areas. It allows for regional and local differences and provides for flexibility in terms of organization and management structure. It has as its philosophy that SSA will continue to provide service that is tailored to the needs of the public, including new and innovative approaches to service delivery. SSA will continue the tradition of maintaining "full-service" facilities. The public may contact us at the facility in person, by telephone, or by mail, and that facility will be able to respond fully to the individual's need for service.

The primary thrust of this methodology is to provide a sound management approach to our delivery of services. This review process may result in the creation of new facilities, possible closing of some current offices or consolidations of facilities (due to population shifts or rapid growth areas), and/or other approaches to service delivery. In developing new approaches which differ significantly from the status quo, regions may wish to consider experimental rather than permanent facilities in some cases.

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The "best" service delivery approaches will depend on local circumstances and will vary from place to place. These procedures will ensure that the same important factors are considered in evaluating different approaches in all reviews. The review is cyclical in nature and has recurring timeframes, and will include a complete review of all district offices, branch offices, resident stations, teleservice centers and contact stations. After the first series of reviews, all service areas will be reviewed on a cyclical basis--each cycle should not exceed 5 years.

The service delivery project (SDP) methodology comprises several procedures and steps designed to be accomplished by the regions:

- o Identify the service areas to be reviewed.
- o Identify service needs, current and projected, for the geographical area of review. These service needs will be used to project workloads and staffing needs.
- o Develop possible options for service delivery. These approaches to placement size and function of facilities will be done initially without regard to existing facilities and personnel. The status quo is always an option to be considered.
- o Apply a uniform cost/benefit analysis and decision support procedure to each option under consideration. Select the best options for the geographical area of review and integrate the "best" options into a consistent service delivery plan for the entire review site.
- o Submit interim reports and a final comprehensive regional plan on service delivery to central office including an action plan and timetables for implementation.

The first review of all service areas will extend from April 1, 1985 to December 31 1987. After this first 2 1/2 year cycle, all geographical areas will be reviewed every 5 years. All service areas will receive a complete and indepth review based on the procedures in sections III, IV and V.

II. Identify the Service Areas to be Reviewed

A. Identify the First Service Areas to be Reviewed

In assessing the current methods of service delivery in the region a method for determining which facilities should be reviewed first has been developed. The following screening criteria should be applied to facilities to identify offices to be reviewed initially.

If individual facilities are identified for the initial reviews, the overall geographical area, including all service areas which are geographically or organizationally related, will be reviewed at the same time. For example, if a branch is identified as a facility to be reviewed initially, the entire district will be reviewed at the same time. If one district in a metropolitan area is initially reviewed, the other districts in the same city should generally be reviewed at the same time.

1. Office Size

- o DO/BO's with a staff size of 10 or less should be reviewed to determine the degree of efficient and cost-effective modes of current operation. Adequate service delivery should be determined.
- o DO/BO's with a staff size of 11-16 should be reviewed to determine the degree of efficient and cost-effective modes of current operation. Adequate service delivery should be determined.

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- DO/BO's with a staff size of 16-25 that are located within 25 miles from another full-service facility, should be reviewed to determine the degree of efficient and cost-effective modes of current operation. Adequate service delivery should be determined.

2. Accessibility

- Metropolitan area (urban/suburban) - generally, claimant travel time to the nearest facility should not exceed 1/2 to 1 hour.

- Nonmetropolitan area (rural) - mileage and time involved in reaching a full-service facility varies from one geographic area to another. In general, facilities should be located in major trade centers in the demographic centers of their service areas.

- Regional Commissioners may wish to consider the following additional factors with regard to accessibility criteria:

  - Availability of a teleservice center (TSC) and/or toll-free service

  - Location(s) of other full-service facilities

  - Travel patterns, availability of public transportation, access routes, etc.

3. Other Considerations

- Management vacancies.

- Lease expirations or opportunities to terminate at no cost to the government.

- Space modifications due to the Claims Modernization Project/Field Office Systems Enhancement (CMP/FOSE) or other major changes in facilities.

Application of these screening criteria is optional and will provide a "first cut" identification of facilities requiring additional review and analysis. It is recognized that additional, regionally developed criteria may be appropriate in identifying facilities to be included in this initial review. Other offices which may be impacted by reviews of these facilities should be included in the review. After selection of the offices, the review methodology described in sections III - VI and the geographic factors discussed in II.B. (below) will be applied.

B. Identify the Remaining Service Areas to be Reviewed

The basic area of review can be the entire region an SSA Area Director's Area, a State, city, or county. Significant geographical and demographic factors should be considered in the designation of boundaries of the review area. Once the review is underway, it may be necessary to change the boundaries. Such a change may require additional data gathering or research.

There are certain geographical situations which may dictate the area of review in a particular region. The automatic establishment of service areas which follow State, county or other political boundaries should not be binding. if by ignoring these boundaries service can be delivered more easily from a management or cost/benefit standpoint. The following are examples of geographical situations that may be considered in determining the area of review:

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1. Two large metropolitan centers relatively close together connected by an identifiable suburban corridor - If two such cities lie in different Areas, consideration should be given to extending the area of review to include the two cities and the suburban area between them.

2. A Peninsula or other geographical feature which imposes natural boundaries - In some cases a large peninsula may include more than one Area or more than one State. Combining the entire geographical area for the review should be considered.

3. Conjunction of State boundaries - Where State boundaries are contiguous, consider expanding the area of review beyond State boundaries if appropriate

4. Multiple Areas in large metropolitan areas - Using the entire metropolitan area as the area of review should be considered.

5. State and County boundaries - There are instances in which SSA Areas coincide with States or counties resulting in long, narrow service areas. It may be more cost-effective or efficient to consider service areas which are more square or round in shape so that all areas served are more equally distant from a central facility. Consideration should be given to modifying the area of review to avoid long and narrow service areas.

Regional Commissioners may wish to develop additional screening criteria to assist in the identification of the area of review in this ongoing process. In any case, it is expected that all facilities (DO's/BO's/RS's/CS's/TSC's) in the region will be initially reviewed by December 31, 1987. Subsequent cycles will be 5 years long.

III. Identify Current and Projected Service Needs

The procedures used in determining service needs are based on the assumption that population numbers and population characteristics, including BIFs and RIFs, determine general volumes and types of workloads which, in turn, determine the basic staffing needs of any field facility. This assumption will have to be modified in certain cases (offices with significant workloads stemming from nonresident clients and/or offices with unusually high interviewing workloads).

As described below, demographic data for urban ZIP codes and for rural counties will be obtained. Regions will also acquire maps of the area of review. Such maps are generally available through a variety of State and local agencies (State highway commission, State planning commissions). ZIP code maps of metropolitan areas are often available at no cost. These can be found in telephone directories, and are available in local United States Postal Service city ZIP code directories. ZIP code maps of other areas may be available from local regional planning councils or may be purchased at retail map outlets.

A. Data To Be Considered

The following section describes the specific data that could be obtained and possible sources for obtaining this data.

1. ZIP code or county population data. Source: Current census data; population data by ZIP code (provided by central office).

2. Projections of population changes to 1990. Sources: State and local, such as regional planning councils, State planning commissions, historical census data; ZIP code data (provided by central office).

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3. BIF's and RIF's by ZIP code or service area. Source: BIF and RIF data by ZIP code (provided by central office).

4. Claims Activity/PE Activity. Source: DOWR

5. Staffing figures. Sources: local offices, or fiscal year DOWR summary.

6. Work units. Source: regional MI sections.

7. Questionnaires or surveys - A questionnaire or survey can be completed by the managers or staff in the area of review This questionnaire can assist in gathering information needed in determining the service needs in a specific location. Such a questionnaire can be developed regionally and can ask for information concerning:

   a. Workload distribution in specific ZIP codes or counties;

   b. workload volumes coming from large institutions, schools (parallel activities);

   c. workloads from clients not residing in the service area;

   d. contact stations, their location, frequency of visits, workload volumes, staffing needs, etc.;

   e. use of the telephone for conducting Social Security business; and,

   f. other issues relating to specific service area characteristics (e.g., foreign language issues, educational level, socio-economic factors, etc.).

B. Using Data

1 After the data is obtained, it may be arrayed in such a way as to facilitate the review and analysis.

2. A statistical procedure that may be used to produce forecasting models for workloads and staff in connection with long-range planning can be found in Appendix A.

IV. Identify Approaches for Service Delivery

Because the service delivery reviews represent a comprehensive look at the way SSA does business in the field, various types of service delivery will be examined to determine which is most desirable in terms of costs and noncost factors. For purposes of these reviews, regions are not limited to traditional approaches in terms of configurations (e.g., DO/BO/RS/CS) or management (e.g., AD/DM/BM). The following procedures are designed to assist in identifying different approaches to delivery of service.

A. General Approaches

1. The geographical area under review may be divided into various categories (urban, suburban and rural).

2. General geographical boundaries should be established for these categories.

3. The next step in this phase is the completion of an outline (Exhibit 1, page 10) which gives the overall characteristics of an approach This outline helps to distinguish one approach from another, and to highlight differences between new approaches and the current situation.

4. The status quo may be the best approach

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B. Alternative Organizational/Management Concepts

Various approaches may be considered as alternative ways to deliver service. However, public contact facilities should always provide the full range of services, tailored to the needs of the service area. Some alternative approaches are discussed below.

1. Consolidation of small offices - In some locations (particularly in some urban areas), SSA opened numbers of small offices. Consideration should be given to consolidation of some of these smaller facilities.

2. Independent facilities - Consideration should be given to establishing fully independent facilities in some locations rather than the current district/branch configurations. This approach may be particularly applicable in rural or small urban settings where service areas are spread out and there is little interrelationship between current districts and branches.

3. City Manager concept - In some urban settings there may be a need for day-to-day coordination and decisionmaking to ensure consistency in the way SSA provides service. A "City Manager" could function somewhat differently depending upon specific options. The following are some possible functions:

    a. Supervises all the individual office managers and TSC manager (if applicable).

    b. Reports to an area director, or could be independent of an area director and answer directly to the regional office.

    c. Determines service policy issues for entire city, and is responsible for the performance of all city offices.

    d. Is involved in the operations of all the city offices.

    e. Is responsible for PI/PR policy and procedures for the entire city, and could have a staff for these functions.

    f. Is responsible for allocation of staff in city offices.

4. Management positions only as needed - Assess the need for management and staff positions in offices.

5. Full-service Teleservice Centers - Consider combining all SSA workloads which are appropriate for telephone interviews in one operation.

6. Returning teleservice to individual offices - Consider returning full teleservice functions to individual offices, particularly in nonurban settings.

7. Processing Offices - Consideration should be given to processing offices and interviewing stations, particularly in dense urban settings.

Many technological innovations or creative public contact ideas may be integrated into approaches, or may form the basis for specific configurations. Technological innovations might include "bank-teller" machines in shopping centers or recorded message machines in field facilities. Creative public contact ideas might include "SSA-Mobiles" (motorized vans for public contact), case-worker concept (similiar to state welfare each CR has specific geographical area of responsibility for all SSA workloads).

Changes in operations due to the current CMP/FOSE effort should be integrated into options as appropriate or may form the basis for specific options.

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Regions are not limited to these alternatives, and are not required to consider any or all of them. They are not offered as being "better" than the status quo. They do, however, represent some approaches that may have validity in certain settings. Regions may wish to experiment with one or more of these alternative approaches.

Exhibit 1

GENERAL CONFIGURATION OUTLINE FORMAT

I. Geographic Area Being Considered

A. General description of the approach and the service areas.

1. The facility (field office, teleservice center, experimental unit, etc.).

a. Function: describe the specific workloads, PI/PR, management and other functions of the facility.

b. Staff: describe the general mix of staff and some details of their duties if it varies much from standard field office operations. Also give a general idea of the size of the staff. The detailed staffing mix and size will result from a later analysis of service needs.

Without specifying the grade of the manager or classification of the office, describe proposed duties of the manager if they vary from standard field office operations.

c. Equipment: describe to what extent the facility has SSADARS or sophisticated telephone equipment such as a call distributor. Equipment that impacts on how we offer service (specialized equipment) should be described, including equipment considerations based on implementation of CMP/FOSE.

d. Location: discuss the general location of offices or facilities (e.g., what town, etc.), particularly if their location represents a change from standard field office settings, or if the location aspect is a major feature of the approach.

e. Other Issues: this section should describe any other issues which are important to the configuration being described. This could include workflow and coordination between facilities, workload issues, interviewing issues (face-to-face, telephone), management issues (who controls and manages PI/PR), consistency issues (how is service consistency maintained), etc.

V. Cost/Benefit Analysis Procedures

A. Background

As part of this study, a cost/benefit analysis of the various service delivery options must be conducted to determine the most desirable approach for servicing a geographic area. The procedures provide uniform factors that can be applied to proposed options as well as to the status quo. Additionally, it must be recognized that any decision concerning an option cannot be made solely on the basis of cost, but must also consider various noncost factors that impact on operations and service delivery. Thus, the procedures provide for not only the identification of costs, but the relevant noncost factors that must be considered in the decisionmaking process.

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A computerized computational program, SDPCOST, is available for regions to use in computing facilities costs. This program is accessible by regional Management Information Sections.

A full cost/benefit analysis should be performed for each service approach, including the status quo, that is seriously considered for a service area.

B. Process

This section describes the factors, procedures and worksheets that are to be used in analyzing the various options identified during the study.

1. Factors

Groups of uniform factors will be used in analyzing the various facilities and options. These factors include ongoing costs and noncost factors. The cost factors are determined for each facility and summed to determine the cost of a specific option.

a. Ongoing Costs

These factors will be used to determine the yearly operating costs for the facilities and options being analyzed.

1) Personnel (See Worksheet 1 and Worksheet 2)

This includes the salaries for all employees in a facility. The costs are categorized in two groupings: operations employees - all positions up to and including the firstline supervisor, and management positions as reported in Blocks BA and BD of the DOWR (e.g., Managers, Operations Officers, Operations Analysts, etc.). OS's are not included as management overhead because they are more involved with processing workloads than managing facilities.

2) Space (See Worksheet 2)

This includes the costs of space rentals (to include SLUC).

3) Telephone (See Worksheet 2)

These costs are categorized into two groupings: line costs and equipment costs. Line costs should include the monthly service charge for lines from the local telephone company (e.g. $15 per month per business line) as well as the usage charges associated with these lines. Such usage charges should be based upon average use and should include local message units charged by the local telephone company (e.g., $.07 per message unit) as well as long-distance charges for such toll services as Enterprise, "800" service, OUTWATS service and commerical long-distance charges. Equipment charges should include the monthly charge for leased telephone systems or the maintenance charge for SSA owned telephone systems. Costs for maintenance of SSA owned telephone systems may be obtained by reference to the specific contract for that telephone system. All other telephone costs may be obtained by referring to the office's monthly telephone bill or by consulting the local telephone company, the General Services Administration, the State Public Utilities Commission or the regional office's Field Services Section.

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4) Other Ongoing Costs (see Worksheet 2)

Regions may include other costs (e.g., contact station travel, etc.). However if "other" costs are included for one approach for a geographic area, they must be included for all approaches in the same geographic area as applicable.

b. Noncost Factors

These are factors which are not readily expressed in terms of costs, but are significant issues to be considered in evaluating each option. The noncost factors are evaluated for each option. These factors are:

1) Public service, levels of service and important management issues.

a) Prompt and Accessible Service

This assesses the effect of an option on waiting times, interview times, client travel time to facilities, accessibility of facilities, etc It can be affected by the demographics of a service area the primary mode of service delivery (e.g.. face-to-face, telephone), etc.

b) Timeliness of Action

This measures the time from the initial contact with the visitor/caller to completion of action by the facility (or facilities). It is primarily a measure of processing time for various workloads and is service as measured primarily by internal Agency processes (SSACCS, tallies, etc.).

c) Quality of Action and Service

This assesses the effect on the quality of the workloads processed as well as the quality of the service given (uniformity, courtesy, helpfulness, etc.).

d) Productivity

This measures productivity as affected by an option. It is impacted by various demographic effects, the primary mode of service delivery (e.g.. face-to-face, telephone), staff size, types of workload processed, workflows and equipment, etc.

e) Operational Concerns

This evaluates the potential impact on office operations, including workflows, operating procedures, staff assignments/flexibility, technological innovations or any other concerns directly related to the operation (e.g., interstate service area requiring knowledge of varying State laws, programs, eligibility requirements, etc.).

2) Reaction to potential change, demographic effects and management issues.

a) Public/Local/Congressional Reaction

This assesses the expected local and congressional reaction to a proposed option.

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b) Responsiveness to Demographics

This deals with the responsiveness of an option to local problems, foreign language and/or minority needs, or other special considerations relating to the location or population of a service area.

c) PI/PR, Referral Activities

This measures how an option affects the PI/PR and referral activities in a given geographic area.

d) Union/Employee Reaction

This assesses the potential reaction of unions and employees to an option. This may include the noncost effect of possible employee relocation, redefinition of job responsibilities, position reclassification and other employee issues.

e) Equipment/Space

This assesses the ability to procure equipment and/or space for an option, including constraints (e.g., GSA, budget allocations, lead times, etc.).

3) Other management issues.

a) Staff Allocation

This assesses the impact of an option on field office staffing.

b) Lines of Authority/Span of Control

These deal with the specific supervision of a facility and the span of control of specific managers/supervisors. The evaluation will measure how an option simplifies/complicates direct supervision of the facility or increases/decreases span of control.

c) Interoffice Relationship/Coordination

These measure the effect on workflow coordination and relationships between multiple facilities serving the same area.

d) Classification/Organization

These involve potential changes in office and/or position classification.

2. Evaluation of Factors

If regions use the SDPCOST program, part of Worksheet 1, and all of Worksheet 2 and Worksheet 3 will be automatically completed by the computer program.

a. Cost Factors

1) Costs will be developed for each facility and each option under consideration and for the status quo. Once the costs for a facility have been developed, transfer them to the Facility Cost Worksheet. If the SDPCOST computation program is used, some of these costs will be calculated automatically.

2) Costs for the various facilities in an option will be pulled from the Facility Cost Worksheets and transferred

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to the Option Cost Worksheet. If the SDPCOST Program is used for all facilities in an option at the same time, this worksheet will be automatically completed by the program.

3) Cost data can be obtained from a variety of sources or regions can contact the central office SDP coordinator for assistance. Possible sources include regional data either in printed form or in the Management Information data base, local office records, regional General Services Administration (GSA) offices, local telephone companies, etc.

4) Certain assumptions of costs can be used (e.g., average positions/job salaries). If anything other than actual costs are used, please explain.

b. Noncost Factors

After the costs have been developed the next step is to evaluate the effect of an option on the noncost factors. It is suggested that the noncost factors be evaluated by those persons having knowledge of the service area in question.

c. When all the costs and noncost factors for options in a geographic area have been developed, summarize the data on Worksheet 4: Cost and Noncost Summary Sheet.

d. After all the options for each geographic area are analyzed using the procedures discussed in the above section, determine which option is "best" for each geographic area. The costs of options should be considered along with noncost factors in reaching this decision. If a more costly option is determined to be the "best" approach, rationale should be supplied to explain the way in which factors might offset the costs. The final decision/recommendation should be indicated on Worksheet 4: Cost and Noncost Summary Sheet.

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Worksheet 1

Worksheet 1: STAFFING MIX/SALARY COSTS

FACILITY_____

	Number of Employees	Salary Costs	Total Costs
DH - Grade___			
ADM - Grade___			
OO/SA			
Other Adm. (specify)_____			
Other Adm. (specify)_____			
		Management Subtotal	
OS			
CR T2			
CR T16			
CR GEN			
FR			
SR			
TSR			
DRT			
DC			
Other (specify)_____			
Other (specify)_____			
Other (specify)_____			
Other (specify)_____			
		Operations Subtotal	
	Total		

Note: Complete this worksheet for each facility.

Worksheet 2

Worksheet 2: FACILITY COSTS WORKSHEET

Facility _____

Ongoing Costs (Yearly)

A. Total Personnel Costs (Salaries) _____

B. Space Costs _____

C. Telephone Equipment _____

D. Telephone Lines _____

E. Other _____

Total _____

Note: Complete this worksheet for each facility.

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Worksheet 3

Worksheet 3: OPTION COSTS WORKSHEET

Option _____ (or Status Quo)

Ongoing Costs (Yearly)

A. Total Personnel Costs (Salaries) _____

B. Space Costs _____

C. Telephone Equipment _____

D. Telephone Lines _____

E. Other _____

Total _____ (Enter on Worksheet 4)

Note: Summarize from all Facility Costs Worksheets for one geographical area. Complete one Worksheet 3 for each service delivery approach for the geographical area.

Worksheet 4

Worksheet 4: COST AND NONCOST SUMMARY SHEET

Geographic Area _____	Status Quo	Option 1	Option 2
1. Ongoing costs	_____	_____	_____
2. Narrative Evaluation of Noncost Factors (Be specific in evaluation of key elements. Attach additional sheets).			
3. Decision/Recommendation			

VI. Regional Reports on Service Delivery Reviews

Regional reports on the service delivery reviews will be sent to the Deputy Commissioner, Management and Assessment with a copy to the Deputy Commissioner, Operations. Regional documentation and record copies of service area analyses for all geographical areas, service areas and facilities should be retained in the respective regional office until those geographical areas are reviewed again in the ongoing 5-year cycle.

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A. Regional Review Plans

By May 30, 1985, December 31, 1985 and December 31, 1986, submit a schedule of the service area reviews that the region plans to complete by December 31, 1985, December 31, 1986 and December 31, 1987, respectively. This report should include:

1. The number of geographical areas to be reviewed;

2. the number of facilities in the geographical areas to be reviewed; and,

3. the names and locations of the specific geographical areas to be reviewed, including the current offices in those geographical areas.

B. Quarterly Status Report

On a quarterly basis, submit reports of the progress of the reviews. These should be submitted March 31, June 30 and September 30 (the March 31 report - for 1986 and 1987). They should include:

1. The number of reviews completed to date;

2. the number of reviews underway;

3. the geographical areas and offices involved in the reviews: and,

4. any action that the region is considering recommending or effectuating as a result of the completed reviews.

C. End-of-Year Reports

On or before December 31 1985. December 31, 1986 and December 31, 1987 submit a complete first cycle report. This report should include:

1. Results of reviews and rationale for regional decisions:

2. action plans for consolidating, converting, downgrading, closing or otherwise changing facilities, or for experimentation with other service delivery approaches:

3. necessary documentation to support recommendations for immediate opening or upgrading of facilities (see D below) or experimental facilities; and,

4. timetables for implementation.

D. Proposals for Facilities Changes Requiring Central Office Approval

The service delivery reviews are designed for short as well as long-term planning. Not all changes that regions propose in their service delivery plans will be for immediate implementation. Proposals for immediate facilities changes which regions wish to recommend along with their end-of-year reports will be submitted at that time. Regions should complete such proposals in accordance with instructions in the Administrative Directives System. Proposals which reflect more long-range plans should be submitted at the time the region wishes to make the change.

E. Office Closings or Downgradings

Regions should continue to forward appropriate information to central office on actual closings or downgradings of facilities (see Associate Commissioner for Management, Budget, and Personnel memorandum, October 11, 1984, "Guidelines for Implementing the Authority to Close or Downgrade a Field Office").

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VII. Notification of Congressional Delegations/Other Third Parties

Regions should inform concerned employee organizations, citizens groups, local and State governments and appropriate congressional delegations of any significant changes as a result of the service delivery reviews. Documentation of such contacts should be retained along with regional records of the reviews.

Appendix A

Determining Staff and Workloads

I. Working With The Data

Population numbers, numbers of BIP's and RIP's, etc. can be used to assist in estimating staffing needs or expected workloads for facilities. The following discusses ways to group and use data to assist in assessing service area needs.

A. Grouping the data - the data can be arrayed for:

1. Each metropolitan area;

2. rural counties (may include suburban counties); and,

3. current office service areas.

B. The following is a suggested format for the data variables.

Population and/or BIP's and RIP's/Work Units/Processing Staff

It includes the minimum of necessary variables. Regions may include more variables in their statistical calculations, depending on availability of data (e.g., population or age breakouts, poverty levels, retirement versus disability beneficiaries, etc.).

C. Data for Specific Groupings

1. DO/BO Grouping - This data can be arrayed on a data entry sheet or other medium with little or no changing of the raw data. If there is a teleservice center (TSC) in the area of review, it may be necessary to prorate the TSC work units and staff into the data for individual offices to show that the TSC workloads and resulting staffing needs and those of the offices stem from the same population. Grouping data by DO/BO may be sufficient for purposes of the service area reviews. However, if data is grouped only by DO/BO, it may be necessary to deal with the rural data separately from the urban data because of the differences in service area characteristics.

An optional approach would be to group data by ZIP code for cities and by county for rural or suburban areas. This means of displaying data would give a detailed view of the characteristics of each ZIP/county in the area of review and is discussed below.

2. Rural/Suburan County Grouping

a. A decision must be made as to which counties to include in this grouping. Certain suburban counties may need to be excluded if it is felt they are more closely related to urban populations. Regions may wish to array more than one group of counties for workload and staff forecasting for the area of review.

b. General population, and BIP plus RIP data, can be arrayed without modification

c. For workload and processing staff, special procedures will have to be applied to the DO/BO data to derive county data. This is discussed below.

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1) Derived work units - work unit figures are by office. To determine work units by county, overall work unit figures for an office can be prorated to each county by the percent of that county population to the overall population in an office's service area. The following example illustrates this procedure.

Example: Counties A, B and C are in one DO's service area. The general population and BIF/RIF population of these three counties are shown below.

	General Population	BIF's Plus RIF's
County A	60,430	8,170
County B	16,695	4,105
County C	25,508	3,783
	102,633	16,058

	Percent Population	Percent BIF's + RIF's	Mean Percent
County A	58.9	50.8	54.8 %
County B	16.3	25.6	21.0 %
County C	24.8	23.6	24.2 %
	100.0	100.0	100.0 %

The total work units for the office were 19,110. They can be allocated as follows.

County A - 54.8 % of 19,110 = 10,472 (derived work units)
County B - 21.0 % of 19,110 = 4,013 (derived work units)
County C - 24.2 % of 19,110 = 4,625 (derived work units)

If local knowledge from questionnaires, surveys or other information can estimate more accurately the distribution of workloads among ZIP codes or counties, these should be used to either modify the prorations or to substitute for them. This modification will be necessary to account for certain situations (e.g., workloads from persons not living in the service area, etc.). In certain places, BIF's and RIF's are a much better predictor of expected workloads than population numbers. This is particularly true in new, fast growing metropolitan areas where large population numbers might not include poor, disabled or older populations. In these cases regions may wish to exclude general population from the procedures in a. above.

2) Derived Staff - the same proportions used to distribute work units should be applied to the processing staff numbers for an office to derive staff for each suburban or rural county.

3) If regions have access to more sophisticated data or regional MI statistical packages, other approaches may be used to determine service needs by counties.

4) After arraying data by counties, and deriving a work unit and staff figure for each county, the data can be grouped direc.ly from the data sheet to arrive at general work unit and staff numbers for combinations of counties in facilities' service areas.

3. City ZIP Code Groupings - The service areas of urban and some suburban offices are generally defined in terms of ZIP codes as opposed to counties. A useful grouping for such offices is in terms of ZIP codes.

a. General population and BIF/RIF data can be arrayed without modification.

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b. For workload and processing staff, use the same procedures outlined above for counties, substituting ZIP code figures for county figures.

c. If regions have access to more sophisticated data or regional MI statistical packages, other approaches may be used to determine service needs by ZIP codes.

d. After arraying data by ZIP codes and deriving a work unit and staff figure by ZIP code, the data can be grouped to arrive at general work unit and staff numbers for combinations of ZIP codes in facilities' service areas.

II. Statistical Correlation/Regression Analyses Using Arrayed Data

A correlation/regression analysis indicates how series of numbers interrelate and to what extent they may be interdependent. For example, it is assumed that population generates workloads. A correlation/regression analysis can disclose what volumes of workloads can be expected from a certain population, and how well the numerical relationships can be counted on as an accurate forecast.

This statistical procedure will permit determinations of population, workload volumes and staffing needs for various proposed service areas which result from considering different approaches to service delivery.

For example, assume that Office A serves six city ZIP codes and Office B serves seven city ZIP codes. If by an alternative service option the 13 ZIP codes were distributed among 4 offices (rather than the current 2), what would be the workload volumes and required staff for each of the 4 offices? The results of the correlation/regression analysis will assist in answering this question. Once the numerical relationships are established, the total population and/or BIF's + RIF's for each grouping of ZIP codes can be introduced into a formula and the expected general workload and general staff will result.

The following are procedures for establishing the data base and performing the correlation/regression analyses.

A. Regions can set up the required data in their MI sections.

B. After the data base has been established, correlation/regression analyses can be run either in the regional MI section or in central office. If the statistical procedures are run centrally, the printouts will be sent to the regional office for further analysis.

C. The correlation/regression analyses will produce a variety of statistical data, among which are the coefficient of correlation the slope and the y-intercept.

1. The Coefficient of Correlation - This number is an indicator of the extent to which sets of numbers are interdependent, that is, how increases (or decreases) in one set of numbers are related to increases (or decreases) in another set of numbers. The sets of numbers in this case are the variables which are introduced into the correlation/regression analyses, and are basically population, BIF's and RIF's, work units and required processing staff. For example, the coefficient of correlation will tell us how increases in population (or subsets of population such as BIF's and RIF's) result in related increases in work units for the particular grouping for which data is input.

The coefficient of correlation is expressed in decimals approaching one (e.g., +.97, +.65, etc.) or moving away from one (e.g., -.97, -.77, etc.). The stronger the correlation between sets of numbers, the closer the decimal will approach one (a 1.00 represents a perfect correlation). A negative number indicates that one set of numbers increases as the other

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decreases. A positive number indicates that the numbers move in the same direction.

The coefficient of correlation from each grouping of variables will be used to determine which groupings produce the strongest correlations, and which groupings should be used to assist in forecasting workloads and staff requirements.

Example: Assume that all the ZIP codes for a city represent one grouping of variables. Correlation/regression analyses produced the following coefficients of correlation.

Variables used in the correlation/ regression analysis	Coefficient of Correlation
Population to Work Units	.81
Population + BIF's + RIF's to Work Units	.84
BIF's + RIF's to Work Units	.90

The grouping of selected variables which yields the best correlation in this example is "BIFs + RIFs to Work Units."

2. The Slope and the Y-Intercept - These numbers will be produced by the output from each correlation/regression analysis. They will be used as discussed below.

D. Forecasting Using the Slope and Y-Intercept Numbers - In the above example, the specific combination of variables, "BIF's + RIF's to Work Units," produced the best "model." That is, to forecast work units for this grouping, (all ZIP codes for a city), the best forecaster of the three is "BIF's + RIF's."

The slope and y-intercept, along with the independent variable (which in our example case is the number of BIF's + RIF's) are used in the following standard formula, $y = mx + b$, where m is the slope number. b is the y-intercept number and x is the sum of BIF's + RIF's.

Example: For the variable combination "BIF's + RIF's to Work Units," assume that the slope is 1406.71334, and the y-intercept is -156.76213. To compute work units for any combination of ZIP codes from the group, the BIF's + RIF's for those ZIP's would be introduced into the formula to forecast expected work units:

work units = 1406.71334 x (BIF's + RIF's) + (-156.76213)

Note that the slope and y-intercept numbers will vary with each specific correlation/regression analysis. The above numbers are used as an example only.

E. The results of these procedures will give very general ideas of expected workloads and required processing staff. Local information and knowledge (from sources such as the managers' questionnaire) should be used to refine the results of the above procedures. Such modification is essential to account for such factors as nonresident workloads, high interviewing levels, etc.

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CLOSING FIELD OFFICES IN WISCONSIN

Senator WEICKER. Senator Proxmire.

Senator PROXMIRE. Madame Commissioner, I know you have seen on television the bad cops/good cops routine. The bad cops give the person who is being interrogated a hard time and the good cops come in to protect the suspect. I am going to be the good cop. In the first place, I have great admiration for you. I think you have done a remarkable job in your career. You are exactly the kind of person who should be appointed by every administration. You have worked for the Social Security Administration most of your life, as I understand it. You have done a superb job. You have been recommended again and again for honors. I greatly admire and respect you.

Now let me point out we have a problem in Wisconsin. [Laughter.] If the Social Security Administration cuts staffing by implementing an effective work measurement system, thus enhancing productivity and maintaining a high level of beneficiary services, then I am all for it. However, my Wisconsin constituents have been concerned over rumors of field office closings that would seem to have an adverse impact on your operations.

For example, the March 7 Milwaukee Journal reported that you plan to close a number of field offices in southeastern Wisconsin. Is that the case?

Mrs. MCSTEEN. No; we do not have any plans to close any specific offices. We do have plans to take a look at all offices in the country in the next 3 years to determine what the needs are in the way of personnel.

Senator PROXMIRE. So some of those offices may or may not be closed.

Mrs. MCSTEEN. You are right.

QUALITY ASSURANCE SATELLITE OFFICES

Senator PROXMIRE. The same article indicated you would be closing the nine-person office of quality assurance in Milwaukee. The Milwaukee office's duty is to make sure the Social Security Program is being administered in a cost-effective manner. How can you justify closing the Office of Quality Assurance when this is the kind of information you use to determine whether to close other offices?

Mrs. MCSTEEN. When we established the Office of Assessment, we had central office persons in assessment and we had regional persons, and then we opened what we called satellite offices throughout the regions where we had people closer to the beneficiaries to go out and make onsite visits. What we have done is close some of the satellite offices, and we have diverted that workload to the regional office. It is still being done, but it is being done by the regional office or another satellite.

We have closed a few satellites because we could still continue to do the same kind of work, but do it in a more efficient way.

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Senator PROXMIRE. Senator Burdick asked me to ask a question for him.

Senator BYRD. Is he one of the good guys or bad guys? [Laughter.]

FACTORS IN DECISIONS TO CLOSE OFFICES

Senator PROXMIRE. If I am asking it on his behalf, he has to be a good guy, as well as a Democrat. [Laughter.]

Ms. McSteen, Senator Burdick points out he comes from the most rural State in the union, along with Senator Andrews, with one of the highest proportion of elderly citizens, and he is concerned about the effect Social Security office closures will have in his area. Will geographic distribution and travel time be factors in your decisions to close offices?

Mrs. MCSTEEN. Yes.

Senator PROXMIRE. Will you consider weather as a factor?

Mrs. MCSTEEN. I don't believe weather has been considered a factor.

Senator PROXMIRE. Wouldn't that be a good idea?

Mrs. MCSTEEN. I would consider it after living in Baltimore.

Senator PROXMIRE. You would after living through one of those Wisconsin or North Dakota winters. It is a lot different than being in Florida. [Laughter.]

Mrs. MCSTEEN. Well, as an individual item, I would say that I don't recall seeing weather as a factor. I would consider that as a part of the issue when you talk about distances, however.

Senator PROXMIRE. Do you foresee having enough flexibility to make these factors—geographical distribution, travel time, and weather—overriding factors in a decision about whether or not to close an office?

Mrs. MCSTEEN. Those are all a part of the decisionmaking process—all those factors.

Senator PROXMIRE. Several North Dakota counties have populations in which more than 20 percent of the residents are over 65. These counties are not adjacent to major trade centers, and senior citizens living in them could be adversely affected by your decisions.

Mrs. MCSTEEN. Aged population is a factor of consideration.

Senator PROXMIRE. Commissioner McSteen, I want to thank you very much. I have other questions and I would appreciate it if you would answer them for the record.

Mrs. MCSTEEN. I will be glad to.

Senator BYRD. We ought to hear them so we will be able to follow as to whether you are playing the role of the good guy.

Senator PROXMIRE. When you respond to these, remember they were asked by a very affectionate, highly supportive fan of yours. [Laughter.]

Senator WEICKER. Until the first office in Wisconsin is closed. [Laughter.] Senator Andrews.

GRACE COMMISSION RECOMMENDATION ON CLOSING OFFICES

Senator ANDREWS. Thank you, Mr. Chairman. We are all fans of yours, really. We feel that people should come up through the ranks because you know best then how to run this shop. It has been your

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career, but the thing that bothers me is sitting back here and listening to you say that the Grace Commission said you should shut down these offices. Now, are you driven by the Grace Commission instead of by OMB or instead of your own judgment?

Mrs. McSTEEN. No; I used that reference because Senator Byrd's question was "What do you say about the Select Committee on Aging asking if a certain number of offices are going to be closed?" And I was just trying to show that there are many, many people and organizations in the country that have been bantering about *x* number of offices that are going to be closed.

Senator ANDREWS. I know that, but the rumor that we get from you on the supposedly secret memos and all of the rest that are no memos at all, once we find that although they are here and they are signed off on and all of that, they suddenly became nonentities, it still bothers us because we hear you are planning to cut staffing by 17,000 workers.

Now, we also hear, and a followup to the question my colleague from Wisconsin asked on behalf of the senior Senator from North Dakota, you responded that, yes, we are taking these points into consideration, but we are told again by the grapevine that your people have sent out the word that priority closings for offices will be concentrated on those offices with 10 staff members or less. Is this true or not true?

Mrs. McSTEEN. It is not true. Unfortunately, the grapevine does a great deal of harm, but it is very difficult to get facts out.

SERVICE DELIVERY PLAN

Senator ANDREWS. So you say there is no criteria coming from your office that priority consideration shall be given for closing offices based on the number of employees?

Mrs. McSTEEN. The memo to which you refer was a draft memo indicating that we would formalize our plan for looking at all offices.

Senator ANDREWS. And nowhere did it mention that you would concentrate or look first at those smaller offices?

Mrs. McSTEEN. No; I just had not finished. The plan does indicate that in the 3-year period all offices should be looked at. And we suggested that regional commissioners would want to look at the small offices among the first, generally thinking that if a small office, five or six people, is in existence, we need to know whether that is a cost-effective operation and whether there is a proper delivery of services.

Senator ANDREWS. You have said almost exactly, unless my ears deceive me, Mr. Chairman, what I said was the grapevine telling me that you have, indeed, and in fact suggested that priority consideration be given to closing those small offices.

Mrs. McSTEEN. What I intended to project and what the memo said was that we would look at the offices and consider whether they should be consolidated, or whether they should be upgraded or downgraded. And we suggested that there were various categories of offices—small offices, offices that were close together that might need to be consoli-

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dated, as well as the large offices. Some metropolitan offices are no longer needed because much of the population has moved out.

Senator ANDREWS. Your people also said that you would look to consolidating or shutting down the small offices unless there were overriding considerations. What are those overriding considerations? Were they a part of the memo as well?

Mrs. MCSTEEN. They are part of the plan; yes.

Senator ANDREWS. They are part of the memo. Mr. Sabatini is nodding his head yes. Sometimes you find that better than the verbal answer. Why were you nodding your head yes?

Mr. SABATINI. We would say the overriding considerations are built into the methodology. We want to look at a small office first and look at it in terms of the geographic location of that office; is it an isolated office serving a rural population; is it an office where the demographic characteristics of the population being served necessitate it being there.

The memo does say that this process is not intended to change the status quo for the sake of change, and that in many cases, the status quo is the best arrangement for delivery of service that you could possibly find.

DISTANCE AS A FACTOR IN CLOSING OFFICES

Senator ANDREWS. Well, now, that could indicate that the distance factor is going to be a causative reason for not being shut down. It also could indicate, the way you stated it, it could be a causative agent to shut down.

Now, if they are great distances from each other, is that one of the ones that will stay open, or what?

Mrs. MCSTEEN. It is one of the factors that would be considered.

Senator ANDREWS. In other words, if one office is a great distance from another one, probably it will stay open.

Mrs. MCSTEEN. I cannot answer that on that basis alone.

Senator ANDREWS. Well, then, let me take a couple of other bases into consideration. You mentioned the weather before. You said, well, looking at Baltimore weather, that is tough. Have you ever seen North Dakota weather?

Mrs. MCSTEEN. Yes, I have.

Senator ANDREWS. Can you imagine a disabled elderly person having to drive 100 miles to review a Social Security case in our weather with a wind chill factor of 90 below zero, an old car, not a very good car, and this is what you are forcing them to do?

Mrs. MCSTEEN. We are not forcing anyone to do that, Senator. I realize——

Senator ANDREWS [interposing]. You are if you shut down those offices.

Mrs. MCSTEEN. If we shut down the office, but we have not said we are shutting the office down.

Senator ANDREWS. OK. Now consideration also should be given to the time element. If you shut down and you have said that you have

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targeted these offices with 10 people or less on staff, you are going to force some of our people to drive a minimum of 100 miles, maybe 150 miles in some cases. You always get the time factor when you look at that, and the delay in benefit payments would also be a burden because many of these individuals are totally reliant on Social Security income.

Now, if they have got a problem, they are out there; they don't have a phone. The difference between getting a friend to drive them 30 miles to a Social Security office or trying to find a friend to drive them 130 miles is considerable. Is that going to be taken into account?

Mrs. McSTEEN. Yes.

EFFECT ON PAYMENT ACCURACY

Senator ANDREWS. According to the information that we have, staffing reductions could affect as well the current payment accuracy rate. Have you taken that into account?

Mrs. McSTEEN. Yes; we have. We don't believe that staffing reductions will affect the payment accuracy rate.

Senator ANDREWS. And according to the information we have gotten, even if the accuracy rate dropped by only one-half of 1 percent, the result would be a loss of roughly $1 billion. That is also accurate, isn't it?

Mrs. McSTEEN. We are very concerned about accuracy, and we have taken every step that we know how to take to improve accuracy in our operation. As many of our computations are put on line and not done manually, we will do a better job with accuracy.

WORKLOAD AS A FACTOR

Senator ANDREWS. But what you are telling us is you are doing it on the basis of cost-effectiveness, so I would imagine that in my State where we have four field offices with 10 people or less, in addition to the Williston office managed out of Minot, that based on what you just told me, if the workload per person in those smaller offices is comparable to the workload per person in the larger offices, your tendency would be to keep them open.

Mrs. McSTEEN. The workload is also a factor in determining whether an office should be opened, remain open or be closed.

Senator ANDREWS. Yes; but what kind of a factor? Is, as I stated, it a matter of effective production? If you do *x* number of cases per person in the office in Office *X* and you do relatively the same number of cases per employee in the average offices, then Office *X* shouldn't be a candidate for being shut down, should it?

Mrs. McSTEEN. Well, the number of claims that an individual employee has is not actually material. It is the number of claims in that office and what the population is that produces those claims.

Senator ANDREWS. Well, we have those figures and the figures that we have for the State of North Dakota show that the workload in the small offices is even slightly higher by 10 to 15 percent per employee than the workload in the larger offices. Therefore, everything else being

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equal in the nature of service to the people, you would have no reason to shut the smaller offices down because they are cost-effective; is that not true?

Mrs. McSTEEN. Well, we really are not out to close the small offices. There is no intent to single out one or more offices and say we will close them because they are small. We look at the entire needs of the community and the people in that community.

Senator ANDREWS. That is the way I would like you to do it, but a moment ago you said your memo went out and said we shall look at small offices first.

Mrs. McSTEEN. That is right. We will look at all offices in order to justify that we need an office in that particular location. That is only good business.

CRITERIA IN SERVICE DELIVERY PLAN

Senator ANDREWS. We will wait and see what kind of a memo—could you supply to the committee the actual memo we have been referring to about looking at these offices and closing down and also the information that may have been included in that memo on extreme or unique circumstances that would be justified to keep it open?

Mrs. McSTEEN. Yes; I will be glad to do that, and also the criteria in the service delivery plan. I think that is important.

SYSTEMS MODERNIZATION

Senator ANDREWS. Your justification for these staffing reductions seems to be based on this new computer system. Could you provide for the record just what that system is going to do so that you can justify shutting down this face-to-face contact?

[The information follows:]

IMPROVEMENTS FROM SYSTEMS MODERNIZATION

We expect a major portion of future FTE savings to come from systems improvements, and in particular, from modernization of the Social Security and SSI claims processes. This does not mean that SSA will be reducing face-to-face contact, except in the sense that we expect to be able to help more claimants and beneficiaries during the first visit to an office without the necessity for multiple visits. We believe that SSA can maintain good service to the public with fewer people, primarily as a result of our investment in systems modernization.

Claims modernization will be implemented in stages, beginning first with Social Security claims and later, SSI claims. This project includes improving software, obtaining appropriate hardware, and developing a new national telecommunications system. Modernization will permit SSA to process claims more quickly, with less manual handling and computations. Some of the specific ways in which the new process will save work years and improve processing are:

—Interviewers in SSA field offices will be able to call up on computer terminals any information already on SSA records for each person filing a claim—for example, information on the Social Security master beneficiary record, the supplemental security record, or any pending claims.

—Interviewers also will be able to call up screens for various benefit computations, and they will be able to look at earnings histories or check Social Security account number records via their computer terminals.

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—Screens for each type of claim will be available, which will show the appropriate questions in sequence. Interviewers will enter responses, and the system will check immediately for errors. This will eliminate the extra steps of keying from a written application and waiting overnight to receive error messages.
—Once all the information is entered correctly, the system will print an application for the claimant's signature, establish case control, and request the earnings record. Many of the earnings records will be available immediately, rather than delayed for a day or more.
—The system will automatically diary cases for followup action, if needed; and automated reports of claims pending and cleared will eliminate the need for manual tallies.

Claims modernization will have a significant effect on the way SSA does business, but its purpose is not to discourage face-to-face contact. People will be able to file their claims by phone or in person as they do now.

There are other systems improvements, other than claims modernization, which will save FTE's and enable SSA to reduce employment. For example, some of the specific systems improvements budgeted for fiscal year 1985 and fiscal year 1986 which have already occurred or which are expected to occur before the end of fiscal year 1986 are:

—Automation of the procedure used by field offices to furnish benefit payment information to State welfare agencies;
—Replacement of card readers with scanning devices for case control and folder location in the Office of Central Operations; and
—Improvements to the claims automated processing system to include cases formerly excluded from automated processing.

PROCESSING FUNCTIONS

Senator ANDREWS. Also, it is my understanding there are a number of processing functions that the new system is not equipped to handle. For example, according to my information, the new system lacks the capability to process disability claims and SSI claims: is that correct?

Mrs. MCSTEEN. We started our systems modernization with title II because that is the basic Social Security retirement and disability programs, and from that, we will move to title XVI, the SSI Program, in the next several years.

Senator ANDREWS. But the system right now cannot handle those functions?

Mrs. MCSTEEN. The claims modernization is geared right now only to title II.

Senator ANDREWS. Can it handle address changes, changes in benefit levels and nonreceipt of checks?

Mrs. MCSTEEN. Not at this time.

Senator ANDREWS. When do you expect it to be able to handle this type of work?

Mr. SIMERMEYER. While we have automated these workloads to some degree, we are going to release contracts this year that develop functional specifications for further automation, so it will be a few years before we have that full capability.

Mrs. MCSTEEN. Your question is very pertinent because the processing of our postentitlement activities is one which we are in desperate need of upgrading, and we are very much aware of that.

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Senator ANDREWS. I also hear, and this is one of the things that bothers me, that you lack a formal process to adequately determine what impact these reductions and office closings will actually have. In fact, I understand you are currently in the process of proposing a methodology to assess the justification for field offices and the level of staffing required.

Mrs. MCSTEEN. Our plan right now is to make certain that we take a look at how the 17,000 FTE reduction could impact on the service and/or the public. And the plan that we have is to move ahead; and when we recognize that there might be a problem in the delivery of service, we will take a look at that and pull back, if necessary.

Senator ANDREWS. Well, you don't have this methodology then in place, so at this point in time, you cannot predict or even estimate the effect that all of this will have.

Mrs. MCSTEEN. It is true that we have not in the past projected SSA employment over a 6-year period, and we simply have not had time in the last month or so to say absolutely that this is what is going to happen next year, and the next year and the year after that. A lot depends upon our initiative to ensure that we manage our workloads effectively.

Senator ANDREWS. When this methodology is completed and you then have the information on hand to determine the effectiveness of the small office, and how you can do all of this, will this committee be given a chance to review that methodology and reasons before adjustments are made in numbers of personnel so that we can be basing our decisions on information? You just said you have not gotten the information yet. It is difficult for us to spar in the dark, so to speak. We have seen memo after memo and asked you and found out some other memos floating around.

Will you give the committee which has the responsibility for staffing that methodology when it is, indeed, and in fact——

Mrs. MCSTEEN [interposing]. I will be glad to, if the chairman would like.

Senator ANDREWS. Oh, the chairman would be very interested, I am sure, because the chairman wants to base the decisions of this committee, as do the Members, on facts rather than on wild guesses and purloined documents and hidden memos, and all of the rest. If you could do that, and then we would have a chance to review, Mr. Chairman, what that methodology says, we can look at it in view of our understanding of Connecticut, West Virginia, and North Dakota. Then we will have something to go on. That would be most helpful. Thank you, Mr. Chairman.

Senator BYRD. Mr. Chairman, our colleague left out the name of that Sir Galahad from Wisconsin.

Senator ANDREWS. I wouldn't want to leave out the name of that Sir Galahad from Wisconsin, but I would like to point out to my colleague from West Virginia when he says we shut down the bus lines, my colleague from West Virginia and I didn't shut down the bus lines; it's them other rascals that did that. [Laughter.]

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Senator BYRD. Right.

COMMITTEE CONCERNS ABOUT PROPOSED EMPLOYMENT REDUCTIONS

Senator WEICKER. I think it should be stated that the concerns, and I think I speak for the members of the subcommittee, the concerns of the subcommittee, Mrs. McSteen, do not relate to your abilities or expertise. The fear on the part of the subcommittee is that something is being imposed here from without. I have to sit here day in and day out. I hear from the doctors at NIH as to what ought to be done; then I hear what OMB says you can do. There are no doctors in OMB, but apparently they are the experts on medical science. That is just one example. Then I hear from the educators as to what should be done. Then I see the system devised by OMB. Nobody pretends to be an educator over there. I think the committee has full confidence—we are very proud of you as being somebody who knows the subject matter, not a political type, rather an expert in the field.

I think there is a wariness here, however, insofar as what is being done as to how this relates to you as compared to how it relates to somebody without, OMB. Take that concern and you match it up with the statistics of an ever-increasing elderly population along with a cutback in services, as has been done in other areas also and there is a certain apprehension on the part of the Members and a certain skepticism as to what it is that is being proposed in the way of these cutbacks.

I think maybe that could be alleviated to some degree by, as has been alluded to by Senator Andrews and Senator Byrd, that I think before this office closing business takes place that you would give to the subcommittee your conclusions on this matter. We need to hear testimony to see whatever is being recommended as a base of fact insofar as the management of Social Security, delivery of services and not—not—any relation to whether or not David Stockman has to get *x* amount of dollars out of the Social Security Administration because he needs *x* amount of dollars over in the Defense Department. That is not our problem. That is some other committee. That is not the problem of my committee.

So I want to reassure you, I really mean that. I think you are an outstanding person, just as Senator Proxmire has said. As I said, I think I have accurately described where the fears come from, where the apprehensions come from. It does not relate to your integrity or to your knowledge.

Senator BYRD. Mr. Chairman, I want to associate myself with you and the remarks you have made. I think it is unfortunate that you have to carry the spear and the shield for someone who isn't in this room. I think, Mr. Chairman, it has been difficult for us in this situation, but we don't have the factors that we need in order to make a judgment on these things. I will look for the factors that will guide you in making decisions.

Mrs. MCSTEEN. We are really not coming to you to ask for your approval and your concurrence in the 17,000 over the long haul because

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the 1985 and 1986 appropriation requests, as you know, only called for a slight downscaling, around 1,700 or 1,900 FTE's in each year, which is fairly normal in our operation. But it is the years beyond 1986 in which we will have the major reductions.

Senator WEICKER. Senator Harkin.

DISABILITY WORKLOADS

Senator HARKIN. Thank you, Mr. Chairman. I don't know if I can add much to what has been said. Perhaps I can add a different dimension, and put a different light on this issue. Picking up where Senator Andrews left off, I just don't understand how you developed this policy. You plan to cut 17,000 employees—what I heard just since I came in the room—yet you have no idea of the impact and don't know what offices are going to be closed. It seems to me a terrible way to make public policy to say you are going to cut so many staff without knowing what the effects are going to be. It seems you need to start the other way around—what your needs are and then how much you can cut.

I am not too excited about this policy anyway. Obviously, it came from the Grace Commission or OMB; I don't know which. It reminds me of what happened 3 or 4 years ago. In 1980, Congress asked the Social Security Administration to do a comprehensive review of disability cases. We didn't say just cut people off. We said to do a review because we had had indications that there were some people receiving benefits who didn't deserve disability.

In 1981, though, that mandate from Congress was changed in the most convoluted policy interpretation I have ever seen. The directive went out to just take people off of disability. I had people in my district, and there are a high proportion of elderly there, who were summarily taken off disability. These were people who had no chance of employment whatsoever, and yet I was told at the time, that no one was denied their Social Security benefits unreasonably. I lined up about five people in a hearing one day. I remember one woman. Her arm was taken off from the elbow down, and she was crippled. Yet she was told that, even though she was crippled, she could do some kind of work with her hands.

We saw case after case, hundreds, I am sure thousands nationwide, of people summarily taken off the disability rolls, or notified they were being taken off which then caused all kinds of anxiety problems because the directive came down.

Well, in Congress we had to come back and ask that the disability beneficiaires be given a face-to-face interview and stop this nonsense of summary removal from the program. That has been done. However, I see the same thing happening here as happened in disability.

What I want to know is not only how these staff cuts are going to impact rural areas, because, obviously, I have an interest in that, too. However, I also want to know how these cuts will affect the disability caseload. How is the Social Security Administration going to implement

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these cuts and still serve the disability cases in any adequate or humane manner as they started doing recently compared to what they were doing a couple of years ago? Have you taken into account how these cuts are going to affect this increasing disability workload?

IMPLEMENTING DISABILITY REFORM LEGISLATION

Mrs. McSTEEN. Yes; we are very concerned. We realize that we absolutely must implement the Disability Benefits Reform Act in a fair and humane way, and we are making every effort to ensure that we get those regulations out. There are 12 such regulations that must be published, and we are involved in the development of those regulations with others, experts outside of the Federal Government, to ensure that we do have the proper evaluation criteria for disability determinations. And we hope to resume the continuing disability reviews by July of this year.

Senator HARKIN. So when will you have the regulations out; in April or May?

Mrs. McSTEEN. They should all be out by the end of April; yes. Then we hope to begin the continuing disability reviews in July. We are in hopes that the face-to-face interviews, as well as the demonstration projects that the amendments require us to undertake, will improve the process and also will add a great deal of humanity to it. We have budgeted for this work in our contingency reserve, and we have asked this committee to approve an increased contingency reserve fund for SSA in fiscal year 1986 because we cannot estimate at this moment what the cost will be for starting up the continuing disability review program again.

Senator HARKIN. There is something wrong here. Do you anticipate that the disability caseload is going to diminish?

Mrs. McSTEEN. Oh, no.

Senator HARKIN. The caseload is going to go up; right? It has to.

Mrs. McSTEEN. Yes; there are 18 court cases, class-action suits, as you know, and 11 of those have been remanded to us as of this time and some 145,000 notices have gone out to disabled individuals advising them of their rights. That workload, along with a review to determine whether medical improvement applies or not, will be a tremendous workload; yes.

ROLE OF STATE AGENCIES

Senator HARKIN. How can you cut 1,600 to 1,900 staff in the next year when you are going to have a tremendous increase in the caseload just on disability mandated face-to-face interviews?

Mrs. McSTEEN. As you know, the disability decisions are made by the State agencies, the disability State agencies in each State, and those employees are State employees. It is true they are funded by Federal dollars, but they are State employees. So they are not affected in any way by a downscaling of our FTE's.

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Senator HARKIN. But the face-to-face interviews also have to occur with the Social Security——

Ms. MCSTEEN [interposing]. Well, the district and branch offices would still be involved in advising the people about the interview, but most of the work will actually be in the review of the cases, as you have indicated, as well as the court cases. So that is where most of the activity will take place, in the State agencies.

Senator HARKIN. Do State agencies have the——

Mrs. MCSTEEN [interposing]. Funds for the State agencies are included in our budget, but our FTE ceilings do not affect State agencies.

Senator HARKIN. Beyond that then there would have to be a review by Social Security if, in fact, the person is denied?

HEARING WORKLOADS

Mrs. MCSTEEN. You are right. If the person appeals, that goes to the Office of Hearings and Appeals; you are right.

Senator HARKIN. My experience has been that the vast majority will appeal.

Mrs. MCSTEEN. Yes; that has been the past experience. You are correct.

Senator HARKIN. Then I guess I get back to the same question. Once your new disability regulations are published, which you say is next month, how many requests for reconsideration and rehearings by those in the current disability cases do you anticipate and will you have adequate staff on board right now or in the next couple of years to handle this?

Mrs. MCSTEEN. We have looked at the workload in the Office of Hearings and Appeals, and we realize that in 1986 the workload should increase as a result of the resumption of reviews of continuing disability. We are looking at bringing back administrative law judges who may have retired and who would consider coming back part-time, because this will be a big one-time workload. So we are looking at ways of accommodating those extra hearings through that effort.

EFFECT OF REDUCTIONS ON THE DISABILITY PROGRAM

Senator HARKIN. You'll be able to handle these extra hearings despite staff reductions of 1,600 or 1,900—is that the number?

Mrs. MCSTEEN. The proposed reduction in the limitation account in fiscal year 1986 is 1,689 FTE's. That is not an unusual figure because our attrition per year is around 5,000. That reduction is normal. It is in the out years, after 1986, that the largest FTE reductions take place.

Senator HARKIN. Have you done any assessment at all on what impact this reduction in personnel will have on the disability program?

Mrs. MCSTEEN. We have projected the needs for implementation of the disability legislation without regard to any downscaling, because we recognize that it is a priority, and we must continue with that. And because of the State agencies, we have somewhat of a——

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Senator HARKIN [interposing]. One final thing. Senator Andrews touched on the issue of your overpayment error rate. Do you have any data at all to show that where you have cut staff in any field office by 21 percent, what the overpayment error rate has been? Do you have any data to show that?

Mrs. MCSTEEN. The error rate?

Senator HARKIN. Yes.

Mr. SABATINI. Senator, over the last 2 years, we have been reduced in size by approximately 6 percent, roughly something in the neighborhood of 2,000 FTE's each year. During recent periods, our error rate in our retirement program has remained stable at about one-half of 1 percent. In the other programs, the error rates have shown improvements. In title XVI, the improvement in recent years has been a significant one.

Senator HARKIN. Is it one-half of 1 percent? What did you say?

Mr. SABATINI. In the title II, the old age retirement and survivors programs, our error rate is approximately one-half of 1 percent. And that has remained stable. An error rate that small you are not going to see swing one way or the other.

Senator HARKIN. There is no movement, you don't have any data——

Mr. SABATINI [interposing]. We have come down, we are smaller today in terms of FTE's than we were 3 years ago.

Senator HARKIN. And the error rate has gone up——

Mr. SABATINI [interposing]. No; the error rate has stayed stable in the retirement program. It has improved in the SSI Program.

Senator HARKIN. It was one-half of 1 percent before that?

Mr. SABATINI. Yes; it stayed stable, and in the SSI Program, it has, in fact, improved.

Senator HARKIN. Will, let me make this final comment. It seems to me what we are seeing is an effort to lay the groundwork for making this program private. If Social Security is full of errors people will get mad at it. Then 3, 4, or 5 years down the road, there will be those who will say, "See, we told you. We have to turn Social Security over to private enterprise." I can imagine a lot of them saying that.

There are a lot of policy people here in this administration and with the Grace Commission who have said all along either all of Social Security or the bulk of it ought to be turned over to private enterprise. I can see this administration taking us down that road, by just taking a number out of thin air and saying implement these cuts. Then 4 or 5 years down the line when you have implemented the cuts and things become unworkable, people will get mad at the program and say, "Let's change it; see, it is not working; Government can't provide those services, so let's turn it over to private enterprise." That, I think, is what may be behind part of this proposal to cut the Social Security Administration's staff.

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TIMING OF PROPOSED EMPLOYMENT REDUCTIONS

Senator WEICKER. As I understand the timing on this matter, and so we don't become unduly concerned to the point of legislating badly, insofar as your evaluation of closings, am I correct in my assumption that that would take the better part of this year to go ahead and make your evaluations as to what it is you are going to do and really probably the impact would not be seen until the budget proposals that we would be hearing appropriations testimony for next year?

Mrs. MCSTEEN. Your assumption is correct, in my opinion.

Senator WEICKER. I will stick to my initial request. I would hope as soon as you have your evaluations done, you would present those to the committee for our review.

Mrs. MCSTEEN. Fine.

Senator WEICKER. For our discussion. It would be foolish, and I certainly am not going to stop in any way your evaluation. You can always improve. But then we want to have something in hand so we know, indeed, this is your judgment, the judgment of your staff as opposed to some outside people coming in and saying knock *x* number. And we can only do that through the assumption.

It is fair to say that any cutbacks now—you are proposing a modest reduction even in this fiscal year; right? Are they part of this overall plan, or is this just your decision on an ongoing basis?

Mrs. MCSTEEN. On an ongoing basis.

Senator WEICKER. It doesn't relate to this new evaluation.

Mrs. MCSTEEN. That is right.

Senator WEICKER. I think we are going to hit this thing head on in the next fiscal year. You will at least have the opportunity to do your evaluation, and we will have the opportunity to question you on that evaluation.

Mrs. MCSTEEN. We would appreciate that.

Senator WEICKER. Senator Domenici has joined us.

PREPARED STATEMENT

Senator DOMENICI. Mr. Chairman, I have been told that the questions I had have been asked, and they are in the record, and we will review them. I have a statement I would like to put in the record.

Senator WEICKER. It will be put in the record.

[The statement follows:]

STATEMENT OF SENATOR PETE V. DOMENICI

I am deeply concerned by recent reports that the Social Security Administration plans to close many field offices, data operations centers, and other installations. These reports cause a lot of pain for Social Security recipients who fear that they won't have anywhere to go for help when they need it and for many good Federal employees who fear that they may lose their jobs.

I want to ensure an adequate level of service to our 37 million Social Security recipients, with as few errors as possible, and at the lowest cost that does not compromise service standards or program integrity. That is a tough job, but one that the Social Security Administration has done well for 50 years.

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It does well because it has good employees. In my home town of Albuquerque we have a data operations center that provides work for hundreds of people. In the past 2 years the manager of that center and his deputy have received awards for their excellent work. I think they are typical of the kind of Federal workers we have in New Mexico. It doesn't strike me as good management to close down or contract out an operation that performs so well.

I also an concerned that any reduction in district offices might have an undue effect on New Mexico. It's a large State with a small population so the Social Security offices are small and widely dispersed. According to the House Aging Committee, New Mexico might lose four offices and another three would be in danger. This would make it very difficult for many New Mexicans to get to a Social Security office.

I hope we can lay to rest today any of these reports that are not factual, and determine exactly what the administration's position is on closing offices or contracting out important tasks.

AFDC QUALITY CONTROL AND EVALUATION OF WORKFARE

Senator DOMENICI. I will submit five questions I don't think have been asked about AFDC quality control and evaluation of AFDC workfare in the States where they have it. If they could submit to the committee an evaluation of what is happening; those questions can be answered for the record, if the chairman pleases.

Senator WEICKER. Absolutely.

Senator DOMENICI. I have no further questions.

BUDGET FOR THE DISABILITY BENEFITS REFORM ACT

Senator WEICKER. Two questions I have remaining here, one relates to the Disability Benefits Reform Act of 1984. Wouldn't it be better to at least have a modest amount in your basic budget to carry out the major new provisions of the law instead of being dependent on OMB to release funds from the contingency reserve?

Mrs. MCSTEEN. It has been almost impossible to predict with any accuracy at all what implementation of the disability legislation is going to require, and we just feel that an increased contingency reserve would be a better way to fund implementation of the disability legislation.

The court cases alone are just absolutely staggering, and we simply don't know what to expect and how many people are going to come in as a result of that. If we could have the additional contingency reserve fund and later very prudently outline our needs and discipline ourselves and not give an unsupportable budget estimate, we feel we would do a better job, and we could be more accountable for it. That is just the way we look at it.

EDUCATION ASSISTANCE

Senator WEICKER. I have further questions for you, Mrs. McSteen, for response for the record. I have a question for Mr. Hawkes and also questions for him for response for the record.

Your budget proposed to eliminate education assistance for refugee children for which Congress provided $16.6 million in fiscal year 1985. Your justification states, "funds which have been provided since 1980 have built the capacity necessary to meet the current special needs of refugee children."

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My question, among others, but the one I am asking here, is the proposed elimination of funding being done with the concurrence of impacted school districts?

Mr. HAWKES. Senator, States and school districts were not consulted or advised in advance of the decision to eliminate funding for education assistance. We have provided over $100 million in assistance for refugee school children since 1980. That money was distributed to build capacity in response to the nearly 300,000 refugees that came in 1980 and 1981.

We are currently receiving something less than 70,000 refugees annually. Therefore, we believe that the capacity to deal with those children has been built by 5 years of appropriations—through the end of fiscal year 1985—and that we don't need to continue a capacity building effort for a much smaller number of children.

Senator WEICKER. In view of ORR's announced intent to bring in additional Asian-American children, will not the elimination of educational assistance increase the burden on the impacted school districts?

Mr. HAWKES. Senator, the number of Asian-American children anticipated to arrive in fiscal year 1985 is very small compared to the total number of the population that is already in place. And, they will be joining Asian-American communities that are already well established. It isn't a new thing for a school district, as it was in 1980.

In 1980, school districts around the country were receiving refugee school children for the first time. A number of them had never dealt with non-English speaking students on any scale before. I think that situation is completely changed now.

[CLERK'S NOTE.—Mr. Hawkes' prepared statement appears on page 1482.]

Senator WEICKER. Are there further questions by any of the Senators of these particular witnesses? It is the request of Senator Chiles that Mr. Simermeyer and Mr. Hawkes stay, even as we move on to HCFA. If necessary, you can come before the committee to respond to those questions. He has a set of questions.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

I thank you all. As I said, there are additional questions for response to the record. I appreciate your testimony before the committee.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

EMPLOYMENT REDUCTIONS

Question. You are proposing to cut 17,000 Social Security staff, through attrition, over 6 years. This includes a reduction of 3,600 full-time equivalent positions by the end of fiscal 1986. If, during implementation of the staffing reduction, it becomes clear that high-quality, timely services to the elderly and disabled are being impaired, will you restore proposed staff cutbacks?

Answer. We are firmly committed to continuation of quality service to the public, and we will do whatever needs to be done to provide that service. The Secretary has received assurance that if there is any glitch in phasing in the new, modernized equipment, there will not be a phasing out of personnel.

Question: Commissioner McSteen, last December you wrote a memorandum to the Assistant Secretary for Management and Budget concerning staff reductions being planned during the FY 1986-FY 1990 time period. Some excerpts from that memorandum are as follows:

> "...the payment error rate could be affected..."
> "...the adverse impact on employee morale will be very real...morale and productivity of any employee forced to change jobs will be low."
> "The longer range impact of these reductions is not easily forecast, but will mean some diminution in the ability to oversee, track and anticipate operational problems in the Agency."
> "The quality of services provided by the offices may be impacted given the significant reduction in management oversight and time to spend on community relations."

Do you still have these same reservations about the proposed staff cuts?

Answer. Neither my memorandum itself, nor the two-page attachment accompanying it contained any of the language you are quoting. Achieving the staff reductions will be a significant management challenge, but I am convinced that we can do it without impairing our quality of service.

Question. Have you factored loss of morale and productivity into your workload projections?

Answer. Our workload projections do not reflect a loss of productivity due to lower employee morale. However, we are aware of the potential effect that any staff reductions may have on employee morale. Over a year ago I initiated a specific Agency objective to manage the impact of automation on our employees and the organization. A project management team was assembled to look at the changes which are to be implemented under the Systems Modernization Plan and elsewhere and to forecast and plan for the various effects on positions and people. The plans will stress

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early identification of displaced employees, active training efforts to prepare them for new assignments, and placement of these employees in vacancies occurring in other parts of the Agency. Continued efforts will help ensure that employees know that we are committed to their continuing to have employment opportunity with SSA, and that we make the most efficient use of our resources to maintain and improve our level of productivity.

SSA has historically been an Agency that has demonstrated concern for employees, and we will continue to ensure that any changes made for the good of the Agency will also consider the effects on employees.

Question. What other negative impacts might result from these massive staff cuts and organizational upheaval?

Answer. We think that automation and other management improvements will result in a better work environment for our employees. Nevertheless, we are proceeding carefully to make needed changes in staffing and organization. As I have mentioned, we have identified management of the impact of automation on our employees and organization as a key Agency objective. Retraining, relocations or other shifts in organizations or staffing patterns will be made with sensitivity to service to the public and to the interests of the employees whose jobs are affected.

SERVICE DELIVERY

Question. Your December 11, 1985, memorandum states: "Efforts will be made through a formal review process of the existing field offices to streamline service delivery. While this could result in eliminating 100 to 200 permanent facilities, we will strive to accomplish the objectives without diminution of service to the public." Shouldn't you do more than strive to avoid diminution of services--by setting a firm policy not to tolerate deterioration of service?

Answer. We want to avoid any deterioration of services. We are firmly committed to a continuation of quality service to the public.

QUALITY OF SERVICE TO THE PUBLIC

Question. Your budget claims that Social Security backlogs have been reduced, workloads are under control, and service to the public has been improved, despite staff reductions. How do you measure the quality of services to the public?

Answer. We do have certain measures which indicate how well we are providing service to the public. Some specific indicators are processing times and error rates. Regarding processing times, recent indicators show improvements in processing times for hearings and most initial claims.

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SSA National Processing Times
in Mean Days

	12/83 Quarter	12/84 Quarter
RSI Initial Claims.....	21.9	19.6
DI Initial Claims.....	70.0	70.7
SSI Aged Claims.....	18.4	14.2
SSI Blind and Disabled Claims..	74.0	73.0
Hearings.....	184	166

Also, backlogs generally have been reduced. For example:

- The number of hearings pending declined from 173,000 at the end of FY 1983 to 108,000 at the end of FY 1984. The present backlog is down to 98,000.

- In the Program Service Centers, we have reduced retirement and survivors insurance claims backlogs by 36 percent from 144,000 in FY 1982 to 92,800 in FY 1984.

- In the Office of Disability Operations, we have reduced disability insurance claims backlogs by 23 percent, from 62,000 in FY 1982 to 48,000 in FY 1984.

- We have reduced the pending level of earnings record requests from a high of 166,000 in February 1983 to 81,000.

RSI payment error rates have remained level in recent periods at about one-half of 1 percent. Most recent data for the SSI program show a payment error rate of 3.4 percent, which has been steadily decreasing from about 5 percent which had been the level for several years prior to FY 1982.

In addition to these objective indicators, various surveys have been conducted by SSA and by outside groups to gauge public opinion about the courtesy of SSA employees and the adequacy of the service SSA provides.

For example, in 1980 the National Commission on Social Security contracted with an independent polling organization to determine the public's opinion on whether SSA gives courteous service. One-third of the people rated SSA "excellent". Another 40 percent rated us "good". The ratings from households receiving survivors or disability benefits were even higher: 45 percent were excellent and 35 percent were good. Ratings from households receiving retirement benefits were higher still: 45 percent were excellent and 43 percent were good.

In 1981, the American Association of Retired Persons and the National Retired Teachers Association contracted with another independent polling organization. This survey was limited to people age 55 and over. Again, people were asked to rate SSA. We were rated high in courtesy by 78 percent of the respondents.

We conducted a recent survey (November 1984 - January 1985) of staff in congressional offices to seek information about perceptions of the quality of SSA service. Congressional staff members were asked to rate 18 aspects of SSA service, such as:

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- o How well are SSA's district office personnel meeting the needs of your constituents?

- o How would you rate the quality of service being provided by the Office of Hearings and Appeals to your constituents?

- o How satisfactory is the written correspondence that you receive from SSA?

The overall mean score was 3.76 on a scale of 1-5.

We will continue to monitor the quality of SSA's service to the public--both in terms of objective indicators like processing times and error rates, as well as in terms of public perceptions--as we move toward modernization and streamlining SSA's service delivery.

Question. How quickly would you know if services to the public began deteriorating?

Answer. We constantly monitor program delivery through ongoing statistical and management information reports. In addition, we have structured and ad hoc communication mechanisms in place between line officials from local managers up to my immmediate office.

I learn quickly of significant events which may affect service from the Regional Commissioners (RC's). A deteriorating trend, e.g., backlogs in individual workloads, is identified at the regional level using weekly workload reports. Two or three weeks of data are usually sufficient to detect trends.

We maintain weekly reports on all major workloads and track the processing and production unit times for each. Reports on accuracy and timeliness are produced monthly. Collectively these reports are very effective in identifying any change in SSA program delivery and in localizing it to a single office or group of offices. SSA's field offices are supervised by a network of Area Directors and regional offices. Through onsite visits and phone calls, Area Directors obtain first hand information about SSA service to the public. Factors adversely affecting public service are either resolved locally or referred to the Area Director, Regional Office (RC's have complete FTE, overtime, and other resources allocated to them for redistribution) or to SSA Headquarters, as necessary.

WAITING TIMES

Question. What information do you have on average waiting times of clients who visit Social Security offices?

Answer. Average waiting times in most offices are generally under 1 hour.

Question. Why not conduct a sample survey to see if Social Security clients are experiencing inordinate delays in being waited on?

Answer. We have done such surveys (nationally) in the past. We perform surveys periodically in the regions and even

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more frequently at the local level. Nationally, average waiting times are well under an hour, and the differences between regional averages are not significant.

Noteworthy differences occur at the local level, reflecting local employee experience levels, hiring problems, demographic influences and the like. Variations occur over time as well, influenced by monthly and weekly cycles (check delivery time, for example), legislation, court decisions on class actions, stories in the media, etc. Waiting times above the average can occur in these instances.

Much management attention has been given to waiting time and reception practices in recent years. We've set up speed lines to handle quick questions, used group interviews for special workloads that affect many people in the same way, emphasized improved reception practices in training and offered telephone service where appropriate, as an alternative to personal visits to our offices. This has contributed to the generally satisfactory waiting time situation, but local and periodic aberrations sometimes occur.

DISABILITY BENEFITS REFORM ACT

Question. On page 235 of your budget justification, you list several major new provisions of the 1984 Disability Benefits Reform Act, including the requirement to review all unfavorable initial and continuing disability determinations made since March 1, 1981, in mental impairment cases. Why is there no specific budget request to handle the additional workload that will be generated from this disability legislation?

Answer. Since the Disability Benefits Reform Act of 1984 was enacted in October, SSA has been working to draft and put in place regulations to implement the major provisions of the legislation and has begun to release them for comment. Due to uncertainties about workloads resulting from this legislation and the final form of regulations to implement the disability amendments, we cannot accurately assess resource needs at this time. For example, right now it is difficult to predict how many will reapply for benefits because of the revised mental impairment standards. In view of these uncertainties, we have proposed increasing the contingency reserve to assure that adequate resources will be available should they be needed.

Question. What is your best current estimate of the additional resources that will be needed in FY 1986 to implement this legislation?

Answer. As I said earlier, we frankly don't know with certainty what additional resources will be needed in FY 1986 to implement the 1984 disability amendments. We believe that the proposed increase to the contingency reserve will assure that adequate resources are available as our needs become clearer.

HEARINGS WORKLOADS

Question. Your budget projects the backlog of disability cases before the Office of Hearings and Appeals will increase by

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34 percent in FY 1986. How much longer will clients have to wait because of this hearings backlog?

Answer. The backlog at the end of FY 1986 is temporary and short-term and reflects the projected status at one point in time, not the intention to keep backlogs at a high level. We anticipate that hearings receipts from continuing disability reviews will create a temporary increase in pending workloads at the end of FY 1986. Right now the number of hearings pending totals about 98,000. At the end of fiscal year 1983 the backlog was more than 173,000. So we have made great progress.

We are quite concerned about clients having to wait for hearings. Average processing time for hearings has been reduced from 184 days in FY 1983 to 166 days by December 1984.

After the moratorium on continuing disability reviews has ended, we expect that appeals from these reviews will begin to be received at OHA about 4 months later. Then OHA will have to process such appeals under the provisions of the Disability Benefits Reform Act of 1984.

Question. Why couldn't you temporarily assign additional administrative law judges (ALJ's) to prevent larger backlogs from developing?

Answer: We are considering employment of additional ALJ's in FY 1986 to handle the anticipated workload increase. We may hire some temporary ALJ's recently retired to prevent a large backlog from developing.

FUNDING FOR FY 1985 PAY RAISE

Question: Last year, Congress added $63 million in the regular FY 1985 Labor-HHS Education Bill to restore 2,850 personnel of the Social Security Administration which the President's budget had proposed be eliminated through attrition. We now understand that this money is being diverted to finance the Federal pay raise which went into effect January 1, 1985. Did you approve this maneuver, which appears to subvert the intent of the Budget Impoundment and Control Act by denying Congress the opportunity to act on a rescission request?

Answer. The Social Security Administration did not need the money for additional personnel. Backlogs are down, processing times have improved and in a number of areas workloads have come in below budget. We prominently featured our need to use the $63 million for other payroll costs in our budget justification (page 204).

Question. In many other places in the budget, the Administration is requesting supplementals to finance the recent Federal pay raise, and simultaneously proposing offsetting rescissions--so what is the rationale for treating the Social Security budget differently?

Answer. We needed the additional funds to meet the costs of the 3.5 percent Federal pay raise, effective January 1985 ($54.2 million), the 0.5 percent retroactive pay raise effective

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January 1984 ($10.4 million), and the employee health benefit increase effective January 1985 ($1.3 million). SSA has experienced workloads below budget and has established staffing levels accordingly. We thought it made more sense to use the $63 million to absorb the increased pay costs within the appropriated amount for FY 1985, thus enabling us to plan our full years' activities rather than waiting until July or August for a supplemental appropriation.

Question. You appear to leave us no alternative but to legislate staffing levels directly in the appropriations bill. Wouldn't it be better for you to honor Appropriations Committee report language directives on stafffing levels, instead of forcing Congress to establish precedents mandating such levels in the law?

Answer. As I stated, SSA's backlogs are down, processing times have improved and the workloads have come in below budget. It is preferable that staffing levels be based on workloads and the ability to process them, rather than to conduct administrative business under a mandatory staffing level set by law.

AFDC FISCAL DISALLOWANCES

Question. Your budget for assistance payments contains an estimate that $173 million will be collected in FY 1985, and another $414 million in FY 1986, from States due to AFDC error rate sanctions. I understand my own State of Connecticut could lose $424,000 just for FY 1981 sanctions alone. If States are forced to pay these amounts, isn't there a danger that services to needy individuals might be adversely affected?

Answer. No. In enacting statutory error rate tolerances, Congress did not intend that benefits to those persons legitimately entitled to benefits be reduced or eliminated. The Michel Conference Report is clear that:

"...under no circumstances are any payments to legitimate recipients to be curtailed or even delayed...."

The potential disallowance amount of $424,000 that you mention for Connecticut represents only 0.4 percent of the State's share of program expenditures for fiscal year 1981. We believe that this potential loss of Federal financial participation (FFP) can be absorbed through better administration of the AFDC program.

Question. When do you expect to begin imposing sanctions?

Answer. The Secretary recently announced her decision on requests from the 28 States which sought waivers for the FY 1981 disallowances. Six of the 28 States received waivers of their disallowances. The remaining 22 States are subject to disallowances for their excess erroneous expenditures.

Disallowance letters will be sent to States shortly advising them of the actual disallowance amount. This letter also advises them how to proceed on the administrative appeal process which is available.

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AFDC QUALITY CONTROL SYSTEM

Question. Do you support legislation to correct defects in the quality control system, so it won't be used in a punitive manner, simply as a budget-cutting device?

Answer. It is a misnomer to describe the quality control (QC) system as either "punitive" or a "budget-cutting device." We believe that the linkage between QC and the error rate disallowance process as mandated by Congress in the Michel Amendment and Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) is a logical extension of the use of the QC system as a comprehensive management information tool for program improvement. By collecting pertinent information from a statistically reliable sample of cases, the QC system provides State management officials with a specific explanation as to the cause of erroneous AFDC expenditures. This information is a necessary prerequisite to the formulation of any reliable strategy for program improvement and error reduction.

If the "budget-cutting device" mentioned in the question refers to the use of QC error rate data to disallow Federal financial participation, then we must emphasize the belief that the threat of disallowances is the primary reason for the marked decrease in the national error rate from 16.5 percent in 1973 to an estimated 6.7 percent in 1983. We further believe that any alteration to the current disallowance structure would likely result in a reversal of this downward trend in the national error rate--resulting in higher Federal and State costs.

We do not believe that the QC system has serious structural defects in need of a legislative remedy. The current QC system has been the subject of numerous studies which have pronounced it both programmatically and statistically sound. Moreover, the system has undergone continual refinement and review within the last 20 years resulting in the development of a methodology for equitably measuring erroneous payments.

PRODUCTIVITY OF STATE WELFARE OFFICES

Question. GAO issued a report in February of 1984 which found that productivity rates of workers involved in processing AFDC applications varied widely among the 15 welfare offices surveyed. What progress has been made to implement a nationwide productivity measurement and reporting system for AFDC, as recommended by GAO?

Answer. We regularly publish State productivity information in the Profile of State Performance in the Aid to Families with Dependent Children Program. In our next report, we will begin using cases per worker as an additional performance measure. However, we have a number of reservations about adopting the system proposed by GAO.

The Department of Health and Human Services expressed a number of concerns regarding the recommendation to establish a nationawide productivity measurement system that came out of the February 2, 1984 Report: Federal and State Initiatives Needed to

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Improve Productivity and Reduce Administrative Costs of the Aid to Families with Dependent Children and Food Stamp Programs. Among these concerns was the fact that GAO incorrectly assumed that the data elements required to assess productivity, as they proposed, were currently and readily available. In addition, GAO's data were based on discussions, workers estimates, and observations, rather than on hard data. While such methods may be acceptable for GAO surveying purposes, we would need to rely on objective data and to use consistent standards of measurement over time.

Also, at the time of the release of the GAO Report, the Office of Family Assistance had a contract to assess data used to evaluate State program performance, including administrative efficiency. Subsequently, the contractor found significant problems with the reliability and comparability of administrative cost data, for the purpose of performance measurement, that would require a considerable effort to resolve. We have found data related to productivity are even less reliable or comparable.

As part of the effort to resolve the issue of data comparability, OFA efforts led to the initiation of an interagency task force to study cost allocation issues, particularly the noncomparability of State cost allocation practices. In addition, OFA has recently reconvened a Performance Standards Advisory Group composed of representatives from other Federal agencies, State AFDC agencies, the APWA, and Family Assistance regional and central office staff. A subgroup of the Advisory Group has also been established to work toward developing an improved measure for assessing the administrative efficiency of State AFDC programs.

Though productivity is a means of assessing program efficiency, we believe that cost efficiency is a more valuable measure of program efficiency than productivity. In fact GAO has, in recent discussions with our staff, indicated that they have also realized the problems entailed in their original recommendation and have been revising their approach to focus more on the issue of cost efficiency.

Question. What is your rationale for proposing an indiscriminate freeze on State administrative costs, without having specific State data on productivity?
Why not develop a system that would reward States that are the most productive?

Answer. We do not feel that the proposed cost cap is indiscriminate. In essence, by limiting costs to their current levels, we are allowing each State to operate at a level the State has demonstrated to be sufficient to administer its AFDC program. While it is true that a great disparity in performance among States appears to exist using indicators of program efficiency, such as cost efficiency or productivity, we do not believe these indicators meet the criteria of reliability and comparability required to develop a fair and equitable performance standard-type system for controlling cost.

It is premature to establish program efficiency standards based on either cost efficiency or productivity to determine rewards until a number of additional issues can be addressed. These issues include:

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--The nonconparability of cost reporting and the reporting of worker hours due to differences in State and allocation practices.

--Legitimate differences in cost or productivity attributable to uncontrollable factors such as differences among States in program workload, demographics, and the general costs of doing business in each State.

--Refinement of performance measures and related data elements.

ESTIMATES FOR WORK OPPORTUNITIES LEGISLATION

Question. You are estimating Federal welfare savings of $197,000,000 and administrative costs of $145,000,000 if Congress enacts your proposed mandatory "work opportunities" legislation. That computes to a savings of $1.36 for each Federal dollar spent. Why is this proposal superior to the existing work incentive program, which is estimated to return $610,000,000 in fiscal 1985 welfare savings, compared to a cost of $256,760,000--or $2.37 saved for each $1.00 spent?

Answer. The WIN method for calculating savings is not comparable to ours. As noted by GAO and others, it vastly overstates WIN savings because it claims savings for job placements which WIN had no role in achieving. It includes savings from employment of individuals who received no benefit from WIN services and of those who received WIN services, but who could have found comparable employment without WIN's assistance.

Our figures, on the other hand, are based upon a measure of the actual net impact of CWEP, job search and related activities on welfare expenditures.

We believe our proposal is superior to WIN in a number of ways because it:

--integrates work activities fully into the welfare system;

--focuses Federal and State efforts on activities which have proven effective;

--requires active participation in work activities rather than merely paper registration;

--extends participation opportunities to individuals who appear harder to employ, but who could gain the greatest benefits from participation. Under the current system, agencies engage in "creaming" of the most employable individuals and frequently avoid the long-term welfare dependents;

--eliminates the problems and inefficiencies of dual agency administration; and

--eliminate the choice between welfare and work for employable individuals.

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ALLOCATION OF ENERGY PROGRAM FUNDS

Question. Due to a change enacted last fall in the formula for State distribution of Low Income Home Energy Assistance funds, many "cold" States would receive less money in fiscal 1986, even if the current national appropriation of $2.1 billion is maintained. Would any States still receive a cut if Congress appropriated the $2,275,000,000 authorized level for fiscal 1986?

Answer. Yes, with an appropriation of $2.275 billion and using the new formula with our current estimates of home energy expenditures by low income households, 11 States would receive slightly less funds in FY 1986 than they did in FY 1985. However, no State would be reduced by more than 5 percent due to the "hold harmless" provision in the recently enacted reauthorization.

In addition, there are a lot of things to look at besides the amount of money appropriated under LIHEAP when examining State service levels. For example, during recent years energy price increases have moderated significantly. States retain the ability to target energy funds, so that a 5 percent reduction in LIHEAP funds, supplemented by increases in other Federal programs, which include energy assistance, does not necessarily mean a reduction in total aid to households.

Question. How much would the nationwide appropriation have to be increased in order to prevent any State from a funding cut?

Answer. The formula in section 604 of the Human Services Reauthorization Act of 1984, P.L. 98-558, directs that LIHEAP funds be distributed according to each State's share of home energy expenditures. For FY 1986, some States are protected from sharp reductions by provisions which result in their receiving a greater share of LIHEAP funds than the proportion represented by their share of home energy expenditures by low income households.

In addition, according to data developed from the Department of Energy's State data systems, Hawaii does not have any measureable share of home energy expenditures by low income households. Therefore, an increase in appropriations would not result in any change for Hawaii.

Using current estimates of home energy expenditures by low income households, total appropriations would have to exceed approximately $3.6 billion before all other States would receive their FY 1985 amounts.

Question. Provide for the record a State-by-State comparison of fiscal 1985 allocations with fiscal 1986 based on: (1) a $2,100,000,000 appropriation; (2) the CBO current services level of $2,159,000,000; and (3) the authorized ceiling of $2,275,000,000.

Answer. The information is shown in the following tables:

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LOW INCOME HOME ENERGY ASSISTANCE PROGRAM
(FUNDING ASSUMPTION $2.1B)

State	FY 1985 Percent	FY 1985 Dollars	FY 1986 1/ Percent	FY 1986 1/ Dollars
Alabama	.874153	18,312,310	.961005	20,133,045
Alaska	.557991	11,689,158	.587145	12,300,683
Arizona	.422751	8,856,051	.464753	9,736,580
Arkansas	.667020	13,973,158	.733292	15,362,464
California	4.689577	98,240,209	4.721758	98,920,771
Colorado	1.589548	33,298,847	1.512760	31,692,305
Connecticut	2.073628	43,439,520	1.973449	41,343,730
Delaware	.283122	5,931,025	.311252	6,520,728
Dist. of Col.	.331267	6,939,598	.364181	7,629,580
Florida	1.383171	28,975,542	1.520597	31,856,487
Georgia	1.093609	22,909,609	1.202265	25,187,437
Hawaii	.107064	2,242,836	.101892	2,134,629
Idaho	.620029	12,988,768	.590077	12,362,111
Illinois	5.903935	123,679,361	5.970695	125,085,993
Indiana	2.643182	55,371,045	2.643182	55,374,634
Iowa	1.841698	38,581,057	1.752730	36,719,670
Kansas	.870034	18,226,012	.872078	18,270,034
Kentucky	1.391091	29,141,451	1.505963	31,549,907
Louisiana	.893687	18,721,526	.982480	20,582,947
Maine	1.343376	28,141,884	1.278480	26,784,147
Maryland	1.633255	34,214,462	1.795528	37,616,296
Massachusetts	4.147929	86,893,426	3.947551	82,701,251
Michigan	5.449081	114,150,782	5.230339	109,575,552
Minnesota	3.925754	82,239,180	3.736110	78,271,455
Mississippi	.749450	15,699,961	.823912	17,260,958
Missouri	2.292550	48,025,791	2.181802	45,708,731
Montana	.727255	15,235,000	.692123	14,499,970
Nebraska	.910790	19,079,813	.866792	18,159,286
Nevada	.198553	4,159,423	.218281	4,572,982
New Hampshire	.785118	16,447,153	.747191	15,653,641
New Jersey	3.961080	82,979,209	4.218217	88,371,605
New Mexico	.514507	10,778,223	.489653	10,258,215
New York	12.573141	263,390,085	11.965759	250,682,523
North Carolina	1.927488	40,378,234	2.110994	44,232,911
North Dakota	.790019	16,549,819	.751855	15,751,354
Ohio	5.222913	109,412,876	5.593527	117,184,333
Oklahoma	.803526	16,832,774	.883361	18,506,402
Oregon	1.231967	25,808,013	1.172453	24,562,876
Pennsylvania	6.753631	141,479,321	6.427377	134,653,486
Rhode Island	.682773	14,303,153	.649789	13,613,081
South Carolina	.694256	14,543,706	.763234	15,989,740
South Dakota	.641634	13,441,352	.610638	12,792,858
Tennessee	1.409145	29,519,666	1.549152	32,454,711
Texas	2.301135	48,205,634	2.529766	52,998,565
Utah	.738667	15,474,052	.702883	14,727,489
Vermont	.588474	12,327,727	.560046	11,732,961
Virginia	1.989488	41,677,041	2.187154	45,820,855
Washington	2.026415	42,450,627	1.928524	40,402,547
West Virginia	.920591	19,285,111	.963361	20,182,409
Wisconsin	3.533743	74,027,070	3.363035	70,455,549
Wyoming	.295746	6,195,470	.281459	5,896,563
	100.00	2/ $2,094,863,121	100.00	3/ $2,094,998,937

1/As of 1 February 1985. The statute requires the Secretary to determine State allocations using the the most recent data available; therefore, these figures may change.
2/Excludes $2,296,000 for Federal administration and .135428 percent for the territories.
3/Excludes $2,160,000 for Federal administration and .135428 percent for the territories.

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Low Income Home Energy Assistance Program
FY 1986 1/
(Funding assumption $2.279B)

State	Percent	Dollars
Alabama	2.148108404	$26,059,327
Alaska	0.587145024	$13,326,785
Arizona	0.555238924	$12,602,602
Arkansas	0.876061014	$19,884,499
California	4.721758054	$107,172,667
Colorado	1.396283234	$31,692,305
Connecticut	1.894692024	$43,004,998
Delaware	0.320352014	$7,271,228
District of Columbia	0.435084994	$9,875,394
Florida	1.816650324	$41,233,637
Georgia	1.436340574	$32,601,512
Hawaii	0.099849804	$2,266,353
Idaho	0.578252404	$13,124,953
Illinois	5.970695004	$135,520,364
Indiana	3.643182024	$39,993,940
Iowa	1.617776284	$36,719,670
Kansas	0.872078034	$19,794,095
Kentucky	1.505963024	$34,181,775
Louisiana	1.173764624	$26,641,683
Maine	1.380062144	$26,784,147
Maryland	1.986318024	$45,084,690
Massachusetts	3.643604754	$82,701,354
Michigan	5.230339054	$118,716,265
Minnesota	3.448443444	$78,271,457
Mississippi	0.984324624	$22,341,825
Missouri	2.067100024	$46,918,249
Montana	0.678253294	$15,394,735
Nebraska	0.849422134	$19,279,860
Nevada	0.260779184	$5,919,066
New Hampshire	0.732217624	$16,619,597
New Jersey	4.218217044	$95,743,485
New Mexico	0.479840174	$10,891,230
New York	11.044441454	$250,682,528
North Carolina	2.532553334	$57,480,234
North Dakota	0.736788314	$16,723,341
Ohio	5.593527064	$126,959,748
Oklahoma	1.055347414	$23,953,874
Oregon	1.082178524	$24,562,876
Pennsylvania	5.932493934	$134,653,489
Rhode Island	0.636768054	$14,453,119
South Carolina	0.911832034	$20,696,416
South Dakota	0.598401154	$13,582,282
Tennessee	1.711428004	$38,845,341
Texas	3.822299944	$86,799,014
Utah	0.688895764	$15,636,294
Vermont	0.548823164	$12,456,979
Virginia	2.373736014	$53,878,157
Washington	1.780034624	$40,402,548
West Virginia	0.963361004	$21,866,801
Wisconsin	3.104094244	$70,455,550
Wyoming	0.278818734	$6,280,428
		$2,269,761,935 2/

1/As of 28 March 1985. The statute requires the Secretary to determine State allocations using the most recent data available; therefore, these figures may change.
2/Excludes $2,160,800 for Federal administration and .135428 percent for the territories.

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Low Income Home Energy Assistance Program
FY 1986 1/
(funding assumption $2.189B)

State	Percent	Dollars
Alabama	1.027010164	$22,320,967
Alaska	0.587145014	$12,646,628
Arizona	0.496674364	$10,697,964
Arkansas	0.783657304	$16,879,344
California	4.721758034	$101,702,845
Colorado	1.471378674	$31,692,305
Connecticut	1.919465394	$41,343,730
Delaware	0.320352024	$6,900,123
District of Columbia	0.389193804	$8,382,919
Florida	1.625036754	$35,001,976
Georgia	1.284840714	$27,674,429
Hawaii	0.099104424	$2,134,629
Idaho	0.573935744	$12,362,111
Illinois	5.970695064	$128,603,937
Indiana	2.643182024	$56,932,001
Iowa	1.704784154	$36,719,670
Kansas	0.872078014	$18,783,854
Kentucky	1.505963034	$32,437,224
Louisiana	1.849960264	$22,615,294
Maine	1.243507624	$26,784,147
Maryland	1.918851374	$41,330,985
Massachusetts	3.839566314	$82,701,154
Michigan	5.230339044	$112,657,268
Minnesota	3.633908964	$78,271,457
Mississippi	0.880501684	$18,965,293
Missouri	2.122119304	$45,708,731
Montana	0.673196124	$14,499,970
Nebraska	0.843081194	$18,159,286
Nevada	0.233273154	$5,024,819
New Hampshire	0.726752614	$15,653,641
New Jersey	4.218217054	$90,856,980
New Mexico	0.476258164	$10,258,215
New York	11.638437874	$250,682,529
North Carolina	2.264534434	$48,776,238
North Dakota	0.731288174	$15,751,355
Ohio	5.593527074	$120,480,844
Oklahoma	0.944033234	$20,333,711
Oregon	1.140380674	$24,562,876
Pennsylvania	6.251557614	$134,653,489
Rhode Island	0.632014574	$13,613,082
South Carolina	0.815655354	$17,568,556
South Dakota	0.593934084	$12,792,859
Tennessee	1.655552884	$35,659,269
Texas	2.703518924	$58,231,609
Utah	0.683753154	$14,727,489
Vermont	0.544726194	$11,732,961
Virginia	2.327375474	$50,135,175
Washington	1.875769134	$40,402,548
West Virginia	0.963361014	$20,750,016
Wisconsin	3.271039844	$70,455,550
Wyoming	0.273759744	$5,896,563
		2/ $2,153,919,031

1/As of 1 April 1985. The statute requires the Secretary to determine State allocations using the most recent data available; therefore, these figures may change.
2/Excludes $2,160,000 for Federal administration and .135428 percent for the territories.

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ENERGY PROGRAM FUNDING

Question. How much would it cost just to bring the losing States up to their fiscal 1985 levels?

Answer. Using current estimates of home energy expenditures by low income households in each State and a funding assumption of $2.1 billion, 25 States experience an aggregate reduction of approximately $56 million from FY 1985 to FY 1986. It should be kept in mind that, due to the operations of the current statutory formula, an increase of $56 million in the total appropriation for LIHEAP would not bring these States up to their FY 1985 amounts.

At $2.1 billion, no State would be reduced by more than about 5 percent, due to the hold harmless provision in the Human Services Reauthorization Act of 1984 (P.L. 98-558). In addtion, there are a lot of things to look at besides the amount of money appropriated under LIHEAP when examining State service levels. For example, during recent years, energy price increases have moderated significantly. States retain the ability to target funds, so that a 5 percent reduction in LIHEAP funds, supplemented by increases in other Federal programs, which provide energy assistance, does not necessarily mean a reduction in total assistance to households.

EFFECT OF ADMINISTRATIVE SAVINGS ON ERROR RATES

Question. Isn't there a danger that if you squeeze Social Security administrative costs too much, you risk losing much larger amounts as accuracy slips and overpayments increase?

Answer. We do not anticipate that our plan to reduce SSA employment will have any adverse impact on error rates. We expect program error rates will remain stable or decrease as a result of the automation and improved procedures which also will allow us to reduce employment. This is so because many errors result from manual handling of claims and other actions. As we increase automation and reduce manual handling, our accuracy rate should improve.

Over the last 2 years, SSA's full-time equivalents have decreased by 6 percent. During that time, program error rates for the old-age and survivors insurance program have remained relatively stable at about 0.5 percent, and error rates for the supplemental security income program have declined.

Question. If there was an increase of just 1 percent in the error rate of Social Security payments, how much more would be erroneously spent each year?

Answer. If program error rates for old-age and survivors insurance payments increased by 1 percent, SSA payments would amount to an additional $1.4 billion. However, as I said earlier, we do not anticipate that our plan to reduce SSA employment will have any adverse impact on the error rates of Social Security payments.

Question. You are requesting to increase contingency reserve funding from $50 million to $175 million, citing workload

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uncertainties associated with the new disability reform legislation, as well as "management of the staffing reduction plan." Why shouldn't we give you this money directly, rather than forcing you to justify the need to OMB before contingency funds could be released?

Answer. As I said before, we've asked for increased resources in the contingency reserve because we do not have a good fix on the amount of money it will take to implement the new disability legislation and the staffing reduction plan. This is exactly the sort of circumstances the contingency reserve was designed for.

USE OF CONTINGENCY FUNDS

Question. If you felt services to the public were beginning to deteriorate, would you seek release of contingency funds for more Social Security staff?

Answer. Yes we are firmly committed to a continuation of quality service to the public, and we will do what needs to be done to assure that we provide quality service.

Question. You are asking for special bill language to authorize use of contingency funds for retraining and relocation of staff, due to the impact of automation and elimination of 17,000 full-time equivalent positions by fiscal 1990. Would you need this bill language irrespective of whether Congress approves your proposed staff cuts?

Answer. The new language proposed would be helpful to SSA. Automation is having an impact on the SSA workforce, and we need to shift employees away from tasks that can now be performed without manual handling. When we make such shifts we may need resources for retraining and relocation. Quite frankly, we do not yet have a fix on these costs, or on the extent to which they can be absorbed without the use of the contingency reserve. Our proposed contingency language is intended to provide the flexibility to handle things such as retraining and relocation of employees once these requirements become more evident.

RELOCATING AND RETRAINING EMPLOYEES

Question. How many people might you potentially have to relocate, based on the fact that attrition patterns tend to vary considerably from area to area around the country?

Answer. At this time we do not know how many employees will have to be relocated geographically. While there will be a number of reassignments of employees from one position to another, many of these will occur in large centers of employment (i.e., headquarters, Program Service Centers) where physical relocation is not generally required. Even in individual field offices, reassignments in some cases can occur in the same office (data review technicians to service representatives) or between relatively nearby offices in the same commuting area. We do anticipate there will be circumstances where physical relocation will be the only answer, but we do not know the extent at this time.

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Question. What would it cost to relocate an employee, on the average, from one city to another nearby city?

Answer. In fiscal year 1984, the average cost to relocate a field office employee was approximately $11,000. This includes costs for temporary housing, broker and real estate commissions, settlement of unexpired leases, house hunting travel expenses and movement of household goods. The FY 1984 experience does not reflect provisions of P.L. 98-151, enacted November 14, 1983, which provides government agencies the opportunity to contract with private firms for relocation services, in the same manner as private industry.

Question. What happens to employees who refuse to move?

Answer. When an employee's job is eliminated, we first try to place the employee in a comparable position within the commuting area. If there are no available positions at the same grade level, the employee is given a choice of taking a position outside the commuting area or taking a downgrade into another available position. If there are no existing jobs open in which to place the employee, the employee will then be given a directed reassignment. Employees who refuse to accept the directed reassignment and/or relocation could be separated from the Federal service under the proper procedural process.

Question. How many employees do you expect may have to learn entirely new jobs?

Answer. The number of employees who may have to learn entirely new jobs has not been determined, and it will not be known until we get further along in our modernization plans. However, a key factor in the process of placing employees into vacancies will be to match skills, grade levels, and geographic locations. Therefore, we expect that a substantial number of reassignments will result in placing employees into parallel positions requiring like skills, knowledge and abilities; e.g., data review technicians to service representatives, program analysts to management analysts, etc. Where substantially new duties must be undertaken by an employee, we are committed to providing the necessary training to make the transition as smooth and productive as possible.

CARRYOVER OF ADP FUNDS

Question. Your budget justification (page 211) shows you don't plan to spend $82 million made available by Congress in fiscal year 1985 for automated data processing and telecommunications. Instead, these funds will be carried over for use in fiscal 1986. Does this indicate your Systems Modernization Plan is behind schedule?

Answer. The Systems Modernization Plan (SMP) is ahead of schedule in some major areas (e. g., replacing and upgrading programmatic and communications host computers, replacing tape files with disk storage devices) and behind schedule in others (e.g., procurement of data communications utility and software modernization). Overall, the SMP is accomplishing what we

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expected it to accomplish. The carryover of unobligated funds reflects the fact that it's difficult to project with precision how much will be obligated in any particular fiscal year in a long-term systems modernization effort.

Question. What are the major reasons for large carryover balances in this area? Specifically, what procurements are lagging? S-43

Answer. There are several reasons for the large carryover of funds from FY 1984, including redefinition of systems design, awards lower than estimates, and delays in acquisition approvals. Over one-half ($63.5 million) of the FY 1984 carryover is attributable to only five major projects:

--Direct Access Storage Device (DASD) Purchase--lease rather than purchase in FY 1984 meant minimal FY 1984 cost.

--Data Communications Utility (DCU) Project--design changes delayed General Services Administration procurement approvals and delayed major acquisition until FY 1985.

--Program Service Center (PSC) Modernization--redefinition of modernization strategy delayed awards until FY 1985 and FY 1986.

--Office Automation Projects--delays in project designs and planning changes caused carryover.

--Telephone Systems Procurement--size and complexity of headquarters replacement system required comments from industry prior to requests for proposals.

Question. How much of your total $210 million request for automatic data processing and telecommunications relates to the Systems Modernization Plan? S-44

Answer. The total amount available for ADP/telecommunications obligations in FY 1985, including carryover from FY 1984, is $224.0 million. Of this amount, about $102 million relates to projects under the Systems Modernization Plan.

SUPPLEMENTAL FOR PAYMENTS
TO SOCIAL SECURITY TRUST FUNDS

Question. You are asking for a $3.5 billion Federal funds supplemental for mandatory payments to Social Security trust funds. Yet your budget justification indicates your actuaries won't have a firm estimate, until September 30, 1985, of the amount required for transfer, and admits the actual need is likely to be less. If these funds won't actually be needed for transfer until October 1985, why do we need a supplemental? Why not wait for either the fiscal 1986 regular bill, or a continuing resolution? S-45,46

Answer. The 1983 Social Security amendments require that any transfer to the trust funds be made within 30 days of the

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actuarial determination of the amount to be transferred. The tentatively scheduled September 30, 1985 determination could occur earlier or later. Rather than wait for fiscal 1986 funding or take chances on the uncertainties of a continuing resolution, we felt it would be better to ensure the money is available so that the trust funds are reimbursed in compliance with the law.

Question. If we did agree to a supplemental, what would you think of adding bill language specifying that "not to exceed" $3,500,000,000 would be available, and limiting actual funding to the amounts certified by the Secretary as necessary once solid data are available?

Answer. We would have no problem with such bill language.

SUPPLEMENTAL FOR TELEPHONE SYSTEMS

Question. You are requesting supplemental appropriation language to use $10,000,000 from unobligated balances in the construction activity for the purchase of telephone systems. When do you actually plan to purchase telephone systems currently being leased?

Answer. SSA has developed a 5-year telephone acquisition plan that projects acquisition of replacement telephone systems on a phased basis for all SSA locations not served by GSA, by January 1, 1989. Replacement of leased systems began in FY 1985.

In summary, the plan calls for competitive procurement of telephone systems as follows:

	FY 85	FY 86	FY 87	FY 88	FY 89
A. Field Offices State Buys.....	12	15	11	9	4
B. Program Service Center Buys.....	2	2	2	--	--
C. Data Operations Center Buys.....	--	--	1	1	1
D. Headquarters System.....	1	--	--	--	--

Question. Do you really need a supplemental, or can this wait for consideration in the fiscal 1986 bill?

Answer. In preparing the FY 1986 budget, we determined that SSA will need an additional $10 million for purchasing automatic call distributors with sophisticated management information capability for the teleservice centers. SSA's budget proposes funding the added costs by transferring $10 million in unobligated funds previously earmarked for field office construction.

Telephone procurement is a lengthy competitive process. Fund commitment is required at the beginning of that process even though the award (obligation) may occur in another fiscal year; hence the need for the reprogramming at this time.

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Question. Why can't you use some of the $82 million you plan to carry forward unspent into fiscal 1986 for telecommunications and automatic data processing?

Answer. All monies carried over are programmed in FY 1986 for approved projects required for implementation of SSA's Systems Modernization Plan and other Information Technology Systems automatic data processing systems. Therefore, in order to provide the funding needed for telephone acquisitions, SSA asked to reprogram $10 million from the construction account, because these funds were no longer needed for construction projects. There are no anticipated requirements or plans for any new construction or expansion projects within SSA at the present time. We felt that it was more prudent to request that these deferred funds be used for telephone acquisitions rather than to seek additional budget authority or to take funds away from those needed for automated data processing projects.

Question. If you purchase telephone equipment and systems which quickly become obsolete, might it not be cheaper to lease than to purchase?

Answer. The telephone equipment and systems we are currently acquiring are expected to have a life cycle of least 5 years. Based on the 5-year life cycle, we find that purchase is cheaper than lease.

AFDC QUALITY CONTROL SYSTEM

Question. The current AFDC quality control system counts paperwork mistakes, such as failure to note all Social Security numbers of family members, in a State's overall error rate. Do you think it is fair to count such technical errors for the purpose of determining fiscal sanctions against the States?

Answer. The Department does not have the latitude to exclude "so-called" technical errors from the calculation of error rates. The law requires States to assure that AFDC applicants meet certain basic eligibility requirements. Compliance with these basic conditions of eligibility as stated in the statute, such as furnishing a Social Security number or registering for WIN, is essential before an individual can qualify for assistance. We have no authority to differentiate between these and other types of payment error nor can we administratively set aside a Federal statute.

Question. Why should mistakes be counted which would not result in benefit payment errors?

Answer. Errors involving basic statutory conditions can have a substantial effect on eligibility or payment amount. These requirements may save program dollars by helping to identify other available means of support from a legally-obligated absent parent, garnished earnings discovered as a result of wage matches using Social Security numbers, or self-support through employment registration.

Furthermore, the Tax Equity and Fiscal Responsibility Act of 1982 eliminated counting these errors for Medicaid because States

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were being charged with errors under both programs for the same requirement. Congress clearly intended that they remain as errors for AFDC.

DISABILITY DEMONSTRATION PROJECTS

Question. The 1980 Social Security Amendments authorized demonstration projects designed to find ways for disabled beneficiaries to return to work. What projects are currently in place?

Answer. Two projects are currently in place for Social Security Disability Insurance (SSDI) beneficiaries, one with Abbott Laboratories, the other with the Electronic Industries Foundation. The Abbott Laboratories demonstration project will determine the employability of persons who are receiving SSDI benefits based on a severe intestinal disorder, such as chronic Crohn's Disease, requiring total parenteral (intravenous) nutrition (TPN). It will test the hypothesis that TPN patients, who ordinarily do not work, can and will work if: they receive TPN services at home rather than at a hospital; their medical costs are covered by a private plan while the patients are employed; and they are assured, since they are so severely disabled, that they will regain their SSDI benefits and Medicare coverage immediately if their disability causes them to stop working.

The Electronic Industries Foundation (EIF) project will test the feasibility of using a national partnership with EIF's Projects With Industry (PWI) network that matches the employment needs of the industry with the skills of disabled workers. EIF's marketing model PWI program provides employers with a central source of qualified handicapped personnel and offers disabled workers immediate access to available jobs. Also, EIF coordinates training programs that provide disabled workers with the skills and qualifications to obtain jobs in the electronics industry.

Question. What projects are planned during FY 1986?

Answer. Our understanding is that we cannot begin any new projects requiring waivers, unless the authorization is renewed or extended by legislation. We are exploring alternative funding authorities for the non-waiver related projects.

Question. Despite the fact that specific authorizing legislation for these demonstration projects expires this June, can you continue these activities under other authorities?

Answer. HHS is seeking general authority to conduct projects of this type.

Although we cannot begin any new projects under section 505, language in the Senate Report on the 1980 Disability Amendments supports continuation of existing projects to validate research findings. The pertinent section of the report states: "The Committee recognizes that some elements of the experimental or demonstration projects may have to remain in effect beyond that date (June 9, 1985) in order to assure the validity of the research."

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In addition, some progress can be made under current authorities when waivers are not required. For example, the first year of the EIF project, FY 1985, is funded under section 1110 of the Social Security Act at a cost of $405,000. Since the EIF project required no waivers, SSA is currently evaluating this and other alternative approaches to funding the project in fiscal year 1986 to avoid disrupting the continuity of the project if there is a delay in reauthorizing the type of authority in the 1980 Disability amendments.

HOUSEHOLDS ELIGIBLE FOR ENERGY ASSISTANCE

Question. Based on 1980 census figures, 22 million households are eligible for Low Income Home Energy Assistance. The FY 1984 program, offering heating, cooling, weatherization, and crisis assistance, served roughly 8.5 million households. Do you agree that the Low Income Home Energy Assistance program serves far fewer households than are actually eligible?

Answer. The statute allows States to make payments to households with incomes under levels which would include about one-fourth of all the households in the nation. So, it is not surprising that, like other assistance programs, LIHEAP does not provide benefits to all the households eligible. The LIHEAP block grant statute provides States with substantial flexibility in setting eligibility criteria within statutory limits. Since LIHEAP is not an entitlement program, States make decisions about how to optimize the number of households served and the level of assistance provided. The LIHEAP statute requires that the highest level of assistance be provided to households with the highest home energy costs in relation to income. We find that States are targetting their LIHEAP payments as the statute requires. Most States set more restrictive income eligibility levels than the maximums allowed by the statute. In addition, States typically screen out households which, for one reason or another, do not bear home energy costs. This also limits the number of households which are eligible according to the criteria which the States actually adopt, and targets assistance on those households which most need assistance. States have broad flexibility under the statute to serve a higher percentage of eligible households if they choose. Using 1980 Decennial Census data, we estimated that States were reaching about one-half the households eligible according to the actual income eligibility criteria they adopted for FY 1983 programs. When we look at the characteristics of these households receiving LIHEAP, we find that they tend to have higher average home energy costs and lower incomes in comparison with other low income households. This seems to us to be very appropriate for a program which is intended to supplement other government programs which also provide help for low income households with their basic needs and housing costs.

Question. What does the Administration suggest to help States serve more eligible households?

Answer. The block grant statute provides States with substantial flexibility in setting eligibility standards for their programs. We have provided States with considerable information from national surveys, such as the Residential Energy Consumption Survey and the Current Population Survey, which include relevant

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characteristics of the households to which the statute allows them to make payments and the households which actually receive LIHEAP assistance. This kind of information helps States make informed decisions about how to optimize the number of households assisted and the level of assistance provided. We also provide forums at annual national conferences for State LIHEAP staff to exchange information and experience about outreach and targetting benefits. We think our appropriate role under the block grant statute is to help the States gather the information they need to make good decisions about targetting assistance, rather than prescribing how they should target assistance. There is nothing in Federal law, regulations or program procedure which prevents States from choosing to use their budget allocations to serve more households in one year than in a prior year.

CHILD SUPPORT ENFORCEMENT

Question. Your budget justification seems to indicate that the child support program will cost more than it saves in welfare benefits for both fiscal years 1985 and 1986. When do you foresee that this program will return more to the Federal Government and the States than it costs?

Answer. In its nine years of existence, the Child Support Enforcement program has consistently returned more to the Federal Government and the States than it costs. Overall savings amounted to $1.4 billion through FY 1984. States have realized $2.2 billion savings in that time while the Federal Government has lost $0.8 billion.

The reason for the disparity in financial returns is that the program's funding stucture was too closely tied to administrative monies spent rather than to results achieved. The Child Support Enforcement Amendments of 1984, however, link incentive payments to the States to collections realized on behalf of both welfare and nonwelfare families and to program cost effectiveness, and gradually reduce Federal financial participation for administrative expenses. The aim is to stimulate more effective and efficient program performance. Also, while a prime focus of the Child Support Enforcement program is to offset and to forestall welfare costs, the program was enacted in the first instance to enforce payment of support obligations owed by parents to their children, locate absent parents, and establish paternity.

Question. How much more would each of the State and Federal shares of collections be in FY 1986, if it were not for the new provision giving $50 per month of collections directly to the AFDC family?

Answer. FY 1986 the State share of collections is reduced by $133 million and the Federal share of collections by $151 million due to giving the $50 per month of collections directly to the AFDC family.

Question. In a report issued last October, GAO found that absent parents paid about half the support owed, and about two-thirds of these parents were delinquent by more than 30 days at least once during the study year. How much of an improvement do you expect to see in these statistics as a result of new

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enforcement tools available under the 1984 Child Support Enforcement Amendments?

Answer. With the mandatory enforcement techniques, we expect significant improvement in the efficiency and effectiveness of the program. Mandatory wage withholding will automatically be initiated when an arrearage equaling no more than one month accrues. This provision alone will reduce the rapid accumulation of arrearages related to chronic nonpayment of support. Expedited legal processes, imposition of liens, and reports to credit agencies, among other provisions, will also help States improve their effectiveness and efficiency in collecting support.

Total collections in FY 1984 were $2.4 billion. With implementation of the mandatory enforcement techniques, we expect collections to grow to $3 billion in FY 1986. In addition, increased savings should result from the families not having to resort to AFDC assistance because they received their child support payments as an outgrowth of support enforcement services.

Question. What steps are you taking to assist the States in carrying out the new law?

Answer. Direct technical assistance to expedite the work of the States in carrying out the new law has included briefing key State decisionmakers on the legislation and its requirements, producing and distributing with the National Conference of State Legislatures (NCSL) a State-by-State analysis of changes needed in existing law, producing and distributing with the American Bar Association a model interstate wage withholding statute, and also with NCSL producing and distributing a compilation of exemplary State legislation related to wage withholding, State income tax offsets, and expediting legal processes.

Another form of assistance to the States has been through increased ADP funding. As a result of the new law, 90 percent Federal funding has been expanded to include, at State option, the acquisition of computer hardware. In addition, the amendments made explicit the availability of preferential Federal matching funds for the development and improvement of income withholding and other mandatory procedures for monitoring child support payments, maintaining accurate payment records, and providing notification to officials about arrearages. We are working with the States to fund projects in these areas.

We are also assisting the States through financial and statistical systems reviews. Through these reviews, we are able to assist the States in determining whether their systems for recording, summarizing, and reporting program collection, expenditure, and statistical data to the Office of Child Support Enforcement are reliable in providing accurate and complete information. If one or more of the State's systems are not reliable, it will impact on program effectiveness, as well as the computation of incentive payments in the future. These reviews enable us to pinpoint deficiencies for State corrective action.

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FACE-TO-FACE AND TELEPHONE CONTACTS

Question. Does your plan to cut Social Security staff assume greater use of the telephone to reduce time spent in face-to-face contacts with clientele?

Answer. We have not budgeted directly for reductions in staffing to come from increased use of the telephone. However, it is true that over the years, in response to changes in the way the public desires to receive service, we have used the telephone more and more.

Question. Hasn't the Congress actually mandated greater use of face-to-face contacts in dealing with disabled clients?

Answer. In October 1982, SSA began face-to-face contacts with beneficiaries in district offices at the beginning of the continuing disability review process to explain to beneficiaries their rights and responsibilities, and to eliminate obviously unnecessary reviews. Now under the disability review process bill enacted in January 1983 (P.L. 97-455), SSA provides beneficiaries who are appealing the termination of their disability benefits, the opportunity for a face-to-face evidentiary hearing at the first level of appeal, known as reconsideration. The majority of these evidentiary hearings will be handled by State Disability Determination Services (DDS) disability examiners. Employment ceilings for the Federal workforce are not applicable to State agencies.

The Social Security Disability Benefits Reform Act of 1984, (P.L. 98-460) enacted in October 1984 includes provision for SSA to test the face-to-face meeting between the beneficiary or new claimant and the State agency at the initial stage of the adjudicative process. The purpose of the test is to determine whether the State agency can better evaluate the claimant's or beneficiary's condition and simplify and expedite the decisionmaking process.

Question. Isn't there a real danger that the level of humane treatment would suffer through impersonal telephone contacts?

Answer. In many cases it is probably more convenient for the beneficiary to be able to get questions answered and problems resolved over the telephone. Part of the planned assessment of service delivery includes addressing the use of the telephone to conduct Social Security business. If some beneficiaries prefer to deal with Social Security by telephone, we will provide that type of service. If face-to-face interviews are found to be necessary for a given population, that also will be available. Many people prefer dealing with us over the telephone, thereby avoiding parking, transportation problems, waiting in the reception area, etc.

VOLUNTARY AGENCY PROGRAM

Question. Your FY 1986 budget states that in FY 1986, private voluntary resettlement organizations would be used to provide for the

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basic needs for refugees for the first 90 days after their arrival in the United States. Further, these agencies would be legally and financially responsible for refugees during this period.

Is it your intention that refugees would cease to be eligible, during these 90 days, for refugee cash assistance or AFDC?

Answer. Yes, we believe it is important to assure that a given refugee could not be receiving duplicative assistance both from the voluntary resettlement agency and from the public welfare agency.

Question. How would this provision be enforced?

Answer. We are currently working on developing a legislative proposal to accomplish this, which could be incorporated as part of section 412 of the Immigration and Nationality Act, the principal section added by the Refugee Act of 1980. However, the final version of such a provision has not yet been decided on. This proposal states that during this period each refugee is precluded from receiving RCA or AFDC.

Question. What effect do you believe this proposal will have on the willingness of voluntary agencies, such as religious organizations, to take on resettlement responsibilities? While churches are able to provide services such as food and shelter, they are not necessarily able to provide financial assistance.

Answer. We have collaborated with the Department of State's Bureau for Refugee Programs, which administers the program of initial resettlement with the voluntary agencies, in developing a proposal that would be acceptable to both voluntary agencies and States. Funds are included in the State Department's FY 1986 budget request which would be intended to enable the voluntary agencies to meet refugees' needs for food, clothing, and shelter during their first 90 days in this country, and the proposal allows agencies to meet refugee needs by providing cash or in-kind aid.

Question. What has been ORR's experience with the efficiency and effectiveness of the work of voluntary agencies in assisting refugees and entrants to resettle in the United States, find employment and particularly to meet their basic needs during the refugees' first six months in the United States?

Answer. As you know, the State Department provides funding through cooperative agreements with the voluntary agencies to provide initial reception and placement services to refugees. These agreements require, among other things, that one month of food and housing be provided to newly arrived refugees, that refugees be counseled on the need to work, and that they be referred to employment services. The agencies have not been required nor have they been funded to provide for the basic needs of refugees for six months nor to find employment for refugees; therefore, I do not think that we can provide relevant data on this request. I think it would be fair to state, however, that the efficiency and effectiveness of the voluntary agencies varies depending upon the agency and the location. Overall, our experience has been that the voluntary agencies are irreplaceable in the resettlement process.

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Question. In connection with the Administration's proposal to use voluntary agencies to assist in refugee resettlement, how much has been included in the State Department budget request for FY 1986?

Answer. According to the State Department's FY 1986 budget request for Migration and Refugee Assistance, its "... requested budget provides $19.4 million for enhanced reception and placement services, through cooperative agreements with private voluntary agencies, to assist refugees to achieve early self-sufficiency and to reduce their dependence on welfare. These services are consistent with an Administration-supported amendment, which the House passed last year, to the Refugee Assistance Extension Act of 1984."

Question. Has this been reflected in any decrease in the funds requested for ORR?

Answer. Since the State Department, in its FY 1986 budget, has requested funds to aid refugees during the first 90 days in the country, ORR's FY 1986 budget request contains no funds for this purpose.

FY 1985 CONTINUING RESOLUTION

Question. The FY 1985 continuing resolution specified that for FY 1985 refugee assistance was to be at the lower of two rates:

— the current rate (i.e., $541.9 million for FY 1984);

— the amount authorized by the refugee extension bill as it had passed the House (i.e., the same or higher than the current rate in all categories except targeted assistance, which was $27.5 million lower).

In the face of this language, how did you determine that the amount appropriated for refugee assistance for FY 1985 was only $444 million?

Answer. The FY 1985 refugee assistance budget under the Continuing Resolution (CR) is the same amount as in FY 1984 for all categories, except targeted assistance, which is limited by the authorization in the refugee extension bill, and cash and medical assistance and related administration (CMA). The latter category is lower in FY 1985 than in FY 1984, primarily because of a smaller 3-year eligible population in FY 1985. The average monthly 3-year eligible population during FY 1984 was approximately 230,000; in FY 1985, the projected average monthly 3-year eligible population is expected to be only about 195,000. As a result, CMA needs in FY 1985 are estimated to be $70.0 million less than in FY 1984. As the Senator has stated, under the provisions of the FY 1985 CR, targeted assistance is limited to the amount authorized by the refugee extension bill as it had passed the House (i.e., $50.0 million, or $27.5 million lower than the FY 1984 amount for targeted assistance). These two items account for the $97.5 million decrease from the FY 1984 level of $541.9 million to the FY 1985 level of $444.4 million.

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Question. The conferees on the FY 1985 Continuing Resolution stated their intent "that $50,000,000 will be available for the targeted assistance program in fiscal year 1985, and that the Department will expend new monies to fulfill the 1985 appropriations levels provided by this bill."

Why did the Department disregard this intent by using $39,026,000 in carry over funds and only $10,974,000 in new budget authority for targeted assistance?

Answer. Under the Continuing Resolution for FY 1985 (P.L. 98-473), $10,974,000 in new funds and $39,026,000 in unobligated funds carried over from FY 1984 will be issued. This is the amount which the Department has determined to be available for FY 1985 under Section 101(k) of the Continuing Resolution which provides funding for the Office of Refugee Resettlement programs "at a rate for operations not in excess of the lower of the current rate or the rate authorized by H.R. 3729 as passed by the House of Representatives. . . ." Since the amount authorized by H.R. 3729 is lower than the current rate (i.e., the amount available for obligation in FY 1984), the amount provided by the Continuing Resolution is the amount authorized in H.R. 3729. H.R. 3729 authorized targeted assistance at the annual rate of $50 million, so that amount is the rate for operations prescribed by the Continuing Resolution for FY 1985.

In determining the amount available for FY 1985, the Department has followed a decision issued by the Comptroller General (58 Comp. Gen. 530,535 (1979)) in interpreting language identical with that used in the Continuing Resolution for the refugee program. The Comptroller General concluded that when a Continuing Resolution appropriates funds to continue an activity at a rate of operations not in excess of a particular rate, any balance of appropriations available from a previous fiscal year must be deducted from the rate prescribed in the Continuing Resolution in determining the amount of new budget authority. If this were not done, the program would be funded at a higher level than that prescribed in the Continuing Resolution.

Therefore, in determining the amount of new budget authority required to provide a rate of operations at the level specified by Congress (i.e., the rate authorized by H.R. 3729) and consistent with the cited opinion of the Comptroller General, the Department has determined that the $39,026,000 in targeted assistance funds which were carried over from FY 1984 must be deducted from the $50 million rate for operations specified by Congress. Thus the amount of new funds required is $10,974,000.

REFUGEE DEPENDENCY

Question. Last year you informed the Subcommittee that, on the basis of ORR's 1983 annual survey of Southeast Asian refugees, 32 percent of those households with refugees who have lived in the United States more than three years were receiving some form of cash assistance (i.e., AFDC, SSI, or general assistance), except in California, where apparently almost all time-expired cases were receiving such assistance.

Have these figures changed in the last year?

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Answer. ORR's 1984 annual survey of Southeast Asian refugees showed that 38.8 percent of households with refugees who have lived in the U.S. more than three years were receiving some form of cash assistance, an increase from the 32.0 percent shown in the 1983 survey.

Question. What accounts for the disparity between California and the rest of the United States?

Answer. Since the enactment of the Refugee Act of 1980, States increasingly have determined refugees to be eligible for the programs of aid to families with dependent children (AFDC) and aid to families with dependent children for unemployed parents (AFDC-UP). This has been especially the case in California. Refugees receiving AFDC-UP in the State have usually been determined to be "unemployable" and therefore not required to seek employment or to participate in employment-directed training. Other AFDC-UP requirements which are inappropriate for refugees (such as the 100-hour rule) are in Federal welfare law and regulations and, under the existing system, apply to refugees and nonrefugees alike. These serve as effective disincentives to any employment by refugees whose inadequate English and lack of occupational skills appropriate to the U.S. job market make it virtually impossible for them to enter the job market at a wage level which would equal or exceed the welfare benefit level for themselves and their families in high benefit States such as California. This problem is more pronounced for refugees than for the general population, because the typically larger size refugee families makes available larger public assistance payments than can be replaced by low wage employment. For example, the California average AFDC benefit for a typical 6-person refugee family is over $800 per month.

Question. If California cases were disregarded, what would the national percentage be of time-expired cases still receiving cash assistance?

Answer. In ORR's 1983 annual sample survey of Southeast Asian refugees (the 1984 analysis is not complete), 65.3 percent of those living in California (both time-eligible and time-expired) were in households receiving cash assistance. In the rest of the U.S., excluding Texas and California, the comparable figure was 34.7 percent. (In Texas it was 8.8 percent.) The contrast between California and the rest of the country has been the general rule for several years. The data are not available, in California or elsewhere, that would permit an exact calculation of dependency among time-expired refugees.

TARGETED ASSISTANCE FUNDING

Question. Given the substantial number of time-expired cases that still appear to require cash assistance, why does ORR believe that the major problems of refugee impact will have been so alleviated, by FY 1986, as to justify elimination of the targeted assistance program?

Answer. In the late 1970s and early 1980s, the large influx of refugees and entrants placed such demands on the service provider infrastructure in major resettlement communities that service

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capacity could not be expanded quickly enough to meet the needs of the incoming populations. Consequently, many refugees/entrants were not afforded services necessary to achieve self-sufficiency. As the number of refugees admitted to the country declined, the targeted assistance program was designed to address the needs of those refugees in the communities most impacted by earlier arrivals.

Present funding provided under the targeted assistance programs of FY 1983 and FY 1984 will cover program operations for the majority of counties through the end of FY 1986. With the three to four years of program funding that targeted assistance awards have made possible, counties have had ample opportunity and resources to significantly address the major problems of past flows so that future needs can be met through the regular allocation of social services funds to the States.

REFUGEE PROGRAM REAUTHORIZATION

Question. When do you expect the Department to submit its proposal for reauthorizing the refugee and entrant assistance program?

Answer. We hope to have such a proposal ready when hearings are held on the reauthorization. The first hearing, in the House, is currently scheduled to be held in April.

WILSON/FISH AMENDMENT

Question. The FY 1985 Continuing Resolution included a legislative provision, known as the Fish amendment, requiring the Secretary to develop and implement alternative projects for refugees in lieu of cash or medical assistance under AFDC or Medicaid. The FY 1986 ORR budget justification (p. 18) notes that such projects are being developed in California and Oregon.

Are any such projects currently in operation? If so, please describe them in more detail.

Answer. There are no projects currently in operation; however, the Oregon and California demonstration projects are in the final stages of development and review.

Question. Have any other States expressed an interest in alternative projects?

Answer. On February 20, 1985, ORR published a preliminary announcement in the Federal Register to implement alternative projects under the Wilson/Fish amendment. The public was invited to comment on the announcement and ORR received a number of comments from States. ORR's regional offices have also received informal expressions of interest in undertaking demonstration projects from several States. Once a final notice is published we expect to learn whether the initial expressions of interest will translate into concrete proposals.

VOLUNTARY AGENCY PROGRAM

Question. Your budget proposes to decrease the Federal matching payment to voluntary agencies to assist in resettlement activities

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from a maximum of $1,000 to $500 per refugee.

Does ORR have any indication that there are private sources of funding that will make up the difference?

Answer. At least one agency currently reports contributions in excess of the amount required.

Question. How is this reduction reconciled with the Administration's proposal to provide funds to voluntary agencies to enable them to take the full legal and financial responsibility for resettlement of refugees during their first 90 days?

Answer. The Administration's proposal will decrease the need for the amount of maintenance support currently provided through the matching grant program. If this proposal is enacted, the Office of Refugee Resettlement will issue a new program announcement for services which promote refugee self-sufficiency. In that event, the announcement will not duplicate requirements embraced in the Administration's proposal.

EDUCATION ASSISTANCE

Question. Your budget proposes to eliminate educational assistance to refugee children, for which Congress provided $16.6 million in FY 1985. The justification states that "funds which have been provided since 1980 have built the capacity necessary to meet the current special needs of refugee children" (p. 26).

What is the specific evidence for this assertion of increased capacity?

Answer. The numbers of refugee children served under this program have consistently declined since 1980, except for the 1981-1982 school year. Refugee children are assimilating very quickly and adjusting to their schools and performing at high levels, while at the same time, the schools have increased their capacity to serve the smaller numbers of new arrivals, as a result of Transition Program funding.

Child count records from State Educational Agencies since 1980 document the sharp decline in eligible refugee children for this program. The highest enrollment figure was in the school year 1981-1982 with approximately 166,716; however, the lowest figure was recorded last school year with approximately 93,920 refugee students. We expect the 1985 child count taken recently to continue this downward trend. These school enrollments reflect reductions in refugee flows and admissions for the last few years.

We believe that with the reduced refugee flows, and the rapid progress of refugee children being mainstreamed into their schools and communities, there is no compelling need to provide additional funds to school districts. Since 1980, educational funding for refugee children has exceeded $100 million to support school districts' capacity to meet the special needs of these children. Moreover, the parents of many refugee children are now employed and paying taxes to support local school systems.

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REFUGEE PLACEMENT POLICY

Question. In December 1983, ORR proposed the designation of certain areas as impacted for the purpose of the placement of refugees. Such areas would be recommended as unavailable for the resettlement of refugees, except in the case of immediate family reunification.

Has this proposal been implemented? If so, with what results?

Answer. The Refugee Assistance Amendments of 1982 require ORR to develop policies and strategies for the placement of refugees in the U.S. This includes the designation of areas of "high impact", which are unavailable for resettlement except in the case of immediate family reunification. In December 1983, ORR published in the Federal Register a proposed regulation to establish a definition of "highly impacted", identify the criteria for applying the definition, and outline procedures for seeking a waiver of the designation. Simultaneously, ORR published a proposed notice which used the definition to identify areas of high impact under the proposed regulation. ORR received many valuable comments and suggestions on the specific proposal as well as on the issue of placement policy in general.

The period of consultation and comment on the development of this regulation was also a period of significant change in the role of placement in refugee resettlement overall. Numbers of new Southeast Asian refugee arrivals are considerably lower (52,000 in FY 1984 and 40,000 in FY 1983) than they were in earlier years (72,000 in FY 1982, 132,000 in FY 1981, and 166,000 in FY 1980). In addition, targeted assistance funds (totalling almost $200 million through FY 1984) have been available to help alleviate problems in areas of greatest need -- particularly those areas affected by high levels of initial placement or by significant secondary migration influxes. The voluntary agencies, operating under revised cooperative agreements with the Bureau for Refugee Programs (RP) in the Department of State, are attempting to avoid placing refugees in areas which they have designated as highly impacted under provisions of the HHS/State placement policy issued in July 1982. Finally, ORR and RP have worked closely with officials in a number of States and localities and with the resettlement agencies to develop planned projects through which groups of refugees could be resettled in areas where local conditions favor their early achievement of self-sufficiency. ORR is also pursuing another approach to improve the resettlement situation -- planned secondary resettlement -- under which select groups of refugees in difficult resettlement areas are assisted in moving to more favorable locations.

At the present time, ORR has not issued a final version of the proposed regulation and does not anticipate doing so. We have considered carefully all of the public comments received and reviewed the discussions held during ORR's FY 1984 national consultation process, and we have examined the current resettlement situation, including arrival rates, activities of the voluntary agencies, and the operation of State refugee programs. We believe that, for the present time and the forseeable future, the policy of July 1982 is sufficient as a guide for the placement of new arrivals.

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VOLUNTARY AGENCY PROGRAM

Question. Your budget proposal for FY 1986 includes a 50% reduction in this matching grant program, and total elimination in FY 1987.

Where is the logic in eliminating this small matching grant program, designed to stimulate private sector support for refugee resettlement, when only a year ago you were actively recruiting organizations to participate?

Answer. In FY 1983, the General Accounting Office issued recommendations to improve the Office of Refugee Resettlement's grants administration process. One of the recommendations was that ORR should increase the monitoring of grants and should seek ways to compete as many of its grant funds as feasible. Therefore, in FY 1984, ORR issued a new program announcement which: 1) specified services and time frames for provision of such services, which in turn provided a better basis against which to monitor grantees; and 2) provided a basis for increasing the number of eligible participants.

This program was initiated in response to a one-time period of high annual rates for South and East European refugees in 1979 and 1980. There is now a diminished need for the program.

AFDC PAYMENT ERRORS

Question. For AFDC, the national average payment error rate has remained well above the September 30, 1982 target rate of 4.0 percent. Do you think that the FY 1983 target error rate of 4.0 percent and the FY 1984 target error rate of 3.0 percent are realistic and fair?

Answer. By attaining these targets, States have demonstrated that the statutory error tolerances are realistic. Based on unofficial estimates, over 25 percent of the States are expected to achieve a 4 percent error rate or less for fiscal year 1983. This issue should be evaluated in light of the extent to which the Federal Government should subsidize excess State erroneous expendutures. Erroneous expenditures for FY 1981 totalled almost $1 billion. The amount subject to disallowance is $73.5 million.

Question. How many States are expected to meet the 3.0 percent error rate level in FY 1984?

Answer. Error rate data for FY 1984 are not yet available, but based on unofficial estimates for FY 1983, approximately 14 States have been successful in lowering their payment error rates to 4 percent or under. It is estimated that one-half of these States held their error rate under 3 percent for that fiscal year.

Question. The FY 1986 budget shows error rate sanction collections of $173 million in FY 1985 and $414 million in FY 1986. What are the assumptions underlying these estimates?

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Answer. Both the Michel Amendment and the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) make provisions for waiving a disallowance should a State fail to attain its target despite a "good faith effort." The amounts shown in the budget are calculated on the assumption that the entire potential for each year will be collected. As we consider State waiver requests, adjustments to the budget may be needed if waivers are granted.

The $173 million total is based on $74 million for FY 1981 and $99 million for FY 1982 of potential disallowance amounts.

Question. Is it realistic to expect sanction collections this fiscal year? Or in fiscal year 1986?

Answer. At the time we were developing the budget for this year, we believed it was reasonable to put in collections for fiscal years 1981 and 1982 to be collected in fiscal year 1985. Since the Secretary has just made her decisions on FY 1981, we will do our best to speed up the process for the fiscal year 1982 waivers. However, it doesn't look as promising for FY 1982 decisions as it did before the beginning of the year when we developed the budget.

Question. Error rate sanction amounts are estimated to be $74 million for FY 1981, $99 million for FY 1982, $180 million for FY 1983, $234 million for FY 1984, $220 million for FY 1985, and $198 million for FY 1986. Where will the States get the money to pay sanction amounts?

Answer. States could absorb any losses of Federal financial participation (FFP) through better administration of the AFDC program. Savings from future error rate reductions should compensate for these proposed disallowances.

Furthermore, the estimated liabilities constitute only an extremely small portion of the AFDC assistance payment expenditures for which the potentially liable States were responsible. For example, the estimated liabilities of $74 million represents only about 2 percent of the $3.6 billion contribution these States made to their total AFDC assistance payment expenditures in FY 1981. The estimated liabilities of $99 million for FY 1982 amounts to 2.2 percent of the States' share of $4.5 billion for that year. Likewise, the FY 1983 potential liabilities of $180 million represents only about 3 percent of the $5.8 billion share of AFDC assistance payment expenditures made by States affected by liabilities.

Question. Will recipients bear the cost by having their AFDC benefits reduced?

Answer. No. In enacting statutory error rate tolerances, Congress did not intend that benefits to those persons legitimately entitled to benefits be reduced or eliminated. As stated in the Michel Conference Report:

"...under no circumstances are any payments to legitimate recipients to be curtailed or even delayed..."

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Question. Since the quality control (QC) system uses a sample of cases rather than the whole caseload, the system can only establish the probability range within which a State's error rate falls. Some observers argue that instead of using the midpoint of the range as the error rate, States should use the lower boundary of the range. Please comment on this. S-94

Answer. The AFDC/QC system uses a regression methodology that takes into account QC findings from the State and Federal samples. The error rate estimated by the regression methodology is a point estimate. Due to sampling variability, one can construct an interval estimate around the point estimate. Your question refers to the point estimate as the midpoint estimate, and refers to the interval estimate as the probability range within which a States's error rate falls.

We use the midpoint estimate as the error rate because the midpoint estimate is generally accepted to be the best statistical measure of the true error rate. The lower boundary would constantly underestimate a State's true error rate.

In addition, the use of the midpoint estimate treats all States equitably. That is, no State is advantaged over another State. If the lower boundary were used as the error rate, States with a greater degree of precision in their estimates are disadvantaged as compared to States with a smaller degree of precision. Two circumstances under which this occurs are: (1) States with large sample sizes are disadvantaged over States with small sample sizes, and (2) States that do high quality QC review work are disadvantaged over States that do poor quality QC review work.

EFFECTS OF DISABILITY BENEFITS REFORM ACT OF 1984

Question. The Disability Amendments of 1984 were intended to soften the intensive review effort launched in 1981, under which many recipients were removed from the disability rolls. Have the softening measures in last year's legislation and other steps taken by SSA and the courts changed the "climate" for making disability decisions?

How much, for instance, have allowances rates on initial claims changed over the past few years?

Answer. The combined initial allowance rates for all types of initial disability claims generally increased over the last four calendar years (1981-30.1 percent, 1982-28.8 percent, 1983-31.6 percent and 1984-34.8 percent). However, quarterly figures since October 1, 1983 indicate that the rates have stabilized in the last year and a half at approximately the 35 percent level, and data for January and February 1985 indicate no change in this trend. These data indicate several things:

- o No significant change in the "climate" has manifested itself in changed allowance rates since the passage of P.L. 98-460, the Disability Benefits Reform Act of 1984.

- o Significant changes did occur in the years 1982 and 1983. This occurred, in part, due to significant actions taken by

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the Department, SSA and Congress to make the continuing disability review (CDR) process more fair and humane. Significant actions included:

--Implementation of the face-to-face interview at the start of each CDR before the case is sent to the State agency for review,

--The issuance of new guides and instructions indicating what constitutes a complete consultative examination medical report,

--Reinforcement of the importance of the application of vocational consideration in cases which cannot be decided on medical grounds,

--Preparation of a basic mental evaluation training package for adjudicators, and

--Implementation of the face-to-face evidentiary hearing at the reconsideration level (P.L. 97-455) in all CDR termination cases (became operational January 1984).

Question. Is it possible that a "looser" administrative climate will lead to a surge in enrollment that could bring on large unanticipated costs and lead to new financing problems with the disability program perhaps before the end of this decade?

Answer. These trends have been considered in the budget estimates and the recently published 1985 OASDI Trustees Report. The following statement from the Trustees Report summarizes the short range effects on the DI trust fund:

"In the short range (and for several decades thereafter), the combined assets of the OASI and DI Trust Funds are estimated to increase each year, on the basis of alternatives I, II-A, and II-B. Based on alternative III, the assets of the OASI Trust Fund are estimated to be more than sufficient to prevent the depletion of the DI fund during the short range."

EFFECTS OF AFDC WORK PROGRAMS

Question. Can you tell us the results to date of the Community Work Experience Programs which are designed to place adult welfare recipients in permanent jobs?

Answer. Thirty-seven States have implemented at least one of the work program options made available in the last 4 years. Twenty-three of these States are operating Community Work Experience Programs (CWEP's). Many of these States (including New York, Oklahoma, West Virginia, Iowa, Georgia, and Pennsylvania) have reported that at least 20 to 30 percent of their CWEP participants are entering regular, unsubsidized employment. Surveys conducted in North Carolina and other States have shown very strong public support for this type of program, as well as improved public attitudes towards welfare recipients.

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Recently we received results from two demonstration projects which show the effectiveness of CWEP and job search requirements in improving the employability of welfare recipients. Both projects used controlled experiments to measure the net impact of participation requirements--or the difference in employment rates for participants and non-participants. In a demonstration in Washington State, in two different sites, 30 and 39 percent of the participants in CWEP and job search activities found employment, compared to a 14 percent placement rate for non-participants. In San Diego, welfare mothers who participated in these programs experienced significant improvement in employment and earnings compared to those receiving WIN services. Employment increased 19 to 23 percent for these mandatory participants, while quarterly earnings increased 28 to 36 percent. Moreover, welfare expenditures for the regular AFDC caseload declined 7 percent and for the AFDC-Unemployed Parents (UP) caseload 14 percent.

Question. How do the welfare savings from Community Work Experience Programs compare to savings being achieved by the Work Incentive Program?

Answer. We cannot provide a direct comparison of CWEP and WIN savings because WIN uses a completely different method of estimating.

WIN savings figures incorporate benefit reductions resulting from employment of any program registrant. They do not take account of the fact that a substantial number of welfare recipients leave the rolls without the assistance of work program activities. To get an accurate measure of savings achieved by WIN, or its net impact, benefit reductions which could be attributed to normal attrition rather than to WIN activities would have to be subtracted from the WIN figures. This adjustment would substantially lower the WIN savings figures. Those studies which have tried to measure the real net impact of WIN have detected little, if any, impact of WIN activities on welfare dependency.

By contrast, our savings estimates are based upon findings of net program impact. They reflect benefit reductions which exceed those expected under normal attrition and which can be attributed to work program requirements. In a controlled experiment in San Diego, California, which included job search combined with CWEP, expenditures on AFDC benefits for the regular caseload were reduced 7 percent, and expenditures for the AFDC-UP program were reduced 14 percent compared to expenditures made under the regular WIN program.

Question. When do you expect to provide Congress with the first year report on WIN demonstration projects required by law?

Answer. We have completed the report and copies will be made available to Congress shortly.

GROWING SOCIAL SECURITY POPULATION

Question. The Leadership Council of Aging Organizations estimates that the elderly population (age 65 and over) is growing by 500,000 individuals each year. Does your plan to cut Social Security staff 25 percent by 1990 take into account the fact that your workload is likely to be much higher by that time?

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Answer. The 1985 Annual Trustees Report indicates that the over age 65 population will grow approximately 11 percent by 1990. With improvements in automation, we can handle more claims and services with fewer people. For example, because of systems improvements in FY 1984, we were able to send out approximately 40 million notices of Social Security income for taxation purposes without increasing our staffing. The aged population has been growing for many years in the past, but with an average 3 percent per year increase in productivity, we handled this while decreasing employment in the past few years.

Question. How many more beneficiaries do you expect to be on the Social Security rolls by 1990?

Answer. By mid-1990, we estimate that 40 million persons will be receiving Old-Age, Survivors and Disability Insurance benefits. This represents an increase of 3.4 million beneficiaries over 1985. During the same 5-year period, we estimate that the number of SSI beneficiaries will increase by 150,000 to 4.2 million.

STATE AFDC ADMINISTRATIVE COSTS

Question. In 1981, the General Accounting Office (GAO) concluded that inadequate review of State AFDC administrative costs may be costing the Federal Government millions in overcharges. What progress has been made to control erroneous State reimbursement claims under the AFDC program?

Answer. The GAO concluded in its report that overcharges were occurring because the Department was not providing its agencies with adequate review guidance, clear cost allocation rules and sufficient staff to accomplish the work. The Department took immediate action, subsequent to the report's issuance, by defining cost monitoring responsibilities of SSA's Office of Family Assistance; establishing a task force to study staffing and workload levels; issuing regulations on development, submission and approval of cost allocation plans; and requiring State cost allocation plans to be amended.

More recently, SSA's Office of Family Assistance developed a Financial Review Guide which contains a section on cost allocation review procedures for our regional and central office staff. The Guide also includes all aspects of the financial review of States' administrative claims, such as internal controls and incentive funding for ADP systems. Extensive training has been given to all staff on the Guide. Based on recent recommended disallowances developed by our staff, the Guide has proven to be of significant value in identifying and processing unallowable cost disallowances. Finally, improvements such as the modernization and consolidation of the data processing resources, will allow the Office of Family Assistance to conduct more detailed analyses of States' administrative budget data.

Question. What action has been taken on GAO's recommendation that you issue guidelines establishing a system of uniform cost principles, procedures, and methodology for all welfare cost-allocation plans?

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Answer. SSA's Office of Family Assistance has worked closely with the Department to issue a contract for a comprehensive review of States' cost allocation methodologies. It is expected that this contract will be in the procurement phase by next month. The purpose of this contract is to identify and document the extent to which (1) cost allocation methodologies and other organizational/program implementation factors affect the variation in costs incurred by program/State, and (2) the extent to which cost data can be used to measure comparable performance. Based upon the results of that study, we will be in a better position to develop uniform cost principles and procedures.

States are afforded a wide latitude in administering the program and, thus, factors such as caseload composition, demographics, and the cost allocation methodologies and procedures of each State vary widely. The variance in State practices makes it difficult to assess performance of State programs. As a result, last year the Department and other Federal agencies formed a study group to assess the current situation and to offer recommendations for improvements, especially with respect to the use of current cost data for measuring comparable performance.

STATUS OF DISABILITY LITIGANTS

Question. What is the current status of people whose disability benefits were re-instituted by the courts?

Answer. P.L. 98-460 requires automatic reevaluation, under the medical improvement standard, of all medical cessations under judicial review or on remand to the Secretary on September 19, 1984, which involve an individual litigant or member of a class action lawsuit. Any person whose case is remanded by the courts is notified of their right to elect to have benefits reinstated pending completion of the redetermination.

As of April 12, 1985, 8,043 cases of an estimated 10,000 individual litigants have been remanded and notified. An additional 4,271 cases have been identified by the Office of Hearings and Appeals (OHA) as remands, and OHA has released notices on all of these cases. About 6,300 individual litigants have requested and received benefit reinstatement.

We have notified approximately 132,500 individuals, covered by 12 class action medical improvement lawsuits remanded to date, of their rights under the new law. As of April 4, 1985, 24,161 class members have contacted SSA and 17,320 of these unnamed litigants have requested reinstatement. We are reinstating benefits to these individuals.

Six class action medical improvement lawsuits, covering approximately 28,000 class members, have not yet been remanded. However, within 2 weeks of receipt of the remand notices, we will release notices to these individuals.

EMPLOYMENT REDUCTIONS THROUGH ATTRITION

Question. You are relying on attrition to absorb staffing cuts. Won't attrition result in losing people from jobs in which you may not need reductions and in places where you won't want to lose them?

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Answer. Across-the-board attrition can result in loss of personnel from areas where we need people. Normally, we rely upon internal promotions or external hires to fill such vacancies. Now, we primarily will be looking at these vacancies as opportunities to place other SSA employees whose jobs have been affected by automation.

Question. If staffing imbalances occur, wouldn't selected reductions-in-force then be called for?

Answer. The Secretary's policy is to avoid reductions-in-force. We plan to resolve staffing imbalances by reassigning employees whose jobs have been eliminated to areas where staffing is needed to handle workloads.

Question. How expensive might it be to retrain and relocate employees if substantial staffing inbalances occur?

Answer. We do not yet know how much money may be needed for retraining and relocation costs. Once we have a better fix on precisely which jobs and which locations will be most affected, we will be in a better position to estimate costs for retraining or relocating those employees.

In our FY 1986 budget request we have proposed language to permit use of the increased contingency reserve to deal with the impact of automation on the workforce. This language is intended to provide the flexibility needed to handle expenses for retraining and relocation of employees.

PLANS FOR CLOSING OFFICES

Question. Do you plan to close any Social Security offices during the balance of FY 1985 and during FY 1986?

Answer. During FY 1984 and early in FY 1985 we approved several branch office closings or consolidations which have not yet been implemented. At present, under our existing procedures, we would estimate that there may be a few closings of branch offices and a few relocations in FY 1985 and FY 1986 --probably not to exceed nine or ten in total for the 2 fiscal years combined.

Question. What timetable do you have for deciding which Social Security offices would be closed, if Congress goes along with your plan to cut staff 25 percent over the next 5 years?

Answer. We have no plan to close specific offices, but let me clarify several points before I address the timetable question. First, we are projecting a 21 percent staff reduction over the next 6 years, not a 25 percent reduction. Second, development of the improved service delivery review process began before the reductions were identified. We would be proceeding with the reviews even if no staffing reductions were planned.

Over the next 3 years, we will be receiving regional office proposals on offices reviewed in the initial effort. There probably will be proposals to consolidate, close, and downgrade

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offices just as there will probably be proposals to upgrade and open offices.

There is no timetable for deciding which Social Security offices would be closed since we have not yet determined that any offices should be closed. The new review procedure gives the regional offices clear and uniform criteria for evaluating their service delivery structure. The first full round of reviews will be completed by December 31, 1987, and future reviews will be conducted on a cyclical basis, with all areas subject to review at least once every 5 years.

ALLOCATION OF RESOURCES

Question. Which local Social Security offices are more backlogged than the average due to heavy staff attrition? Can you pinpoint specific areas where backlogs are severe? What are you doing to correct imbalances between areas of the country where backlogs are severe?

Answer. In our allocations of resources--employment, overtime, travel dollars--we try to prevent or correct imbalances which may occur between workloads and staffing. This includes dealing with temporary, local backlogs which may result from a new workload, such as implementing a court decision, or from unexpected attrition in a local office.

SSA Headquarters reallocates resources to each component and Regional Commissioner throughout the year, primarily on the basis of workloads, as part of the ongoing budget execution process. In turn the Regional Commissioners distribute resources to local levels on the basis of current and anticipated workloads and attrition. In making these allocations, Regional Commissioners consider if particular offices have heavy backlogs or are short-handed because of unexpected employment losses.

Regional Commissioners' offices are in daily contact with area and local offices and learn quickly about special problems which need attention. I learn quickly from the Regional Commissioners significant events which may affect service to the public. A deteriorating trend, such as a growing workload backlog, is identified at the regional level using weekly workload reports. Area Directors obtain first-hand information about SSA service through onsite visits and phone calls. In the event that a situation may be too large for local or regional resources to resolve, resources may be shifted between regions or from other SSA components.

During the rest of FY 1985, FTE allocations to the field will allow, on the average, most district and branch offices to fill each new vacancy which occurs. For FY 1986 SSA's budgeted level of FTE's is only 2.2 percent below the FY 1985 level. Overall, pending caseloads in field offices now are in good shape. However, in filling vacancies we are mindful of offices which may have unusual backlogs or other problems.

Further, one purpose of the Service Delivery Project is to address imbalances in the delivery mechanism or structure. The population in the United States has been shifting to Florida,

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California, and the Southwest, and we may need to gradually adjust our staffing distributions accordingly.

SAFEGUARDS TO STRENGTHEN PROCUREMENT PRACTICES

Question. You plan to acquire 17,500 computer terminals for field offices, as part of your "Claims Modernization Project". What safeguards have been put in place to ensure that poor procurement practices recently documented by the General Accounting Office are not repeated?

Answer. SSA has introduced a number of safeguards to strengthen its procurement practices:

--The use of industry-sponsored architecture/interface requirements enables wide competition by vendors providing field-proven, off-the-shelf equipment that has a broad base of customer acceptance and supplier support, and ensures broad competition to meet future requirements.

--Custom development or enhancements, as well as unique software interface limitations, will be avoided.

--Factory quality assurance procedures will be evaluated and monitored to form a part of the record for each device.

--Acceptance testing procedures will be defined in the Request for Proposal (RFP), and will be demonstrated at the factory and in an expanding tier of pilot installations. Teams of specially designated SSA/contractor support will be used for testing.

--The RFP specifications on major procurements will be released for industry comment and reactions from the General Accounting Office, the General Services Administration and the Department of Health and Human Services. SSA will evaluate all responses and incorporate appropriate recommendations.

--The Operational Capability Demonstration process has been revised to prevent contractor control of the proposed devices.

--The technical review staff reporting to the Deputy Commissioner for Systems will evaluate the technical products and performance throughout the acquisition cycle.

ACQUISITION OF NEW COMPUTER TERMINALS

Question. What is your timetable for acquiring these computer terminals?

Answer. The procurement award for the computer terminals is scheduled for the spring of 1986, with national installation starting in the summer of 1986. Installation is scheduled over a 2 year period.

Question. How much is budgeted for acquiring these terminals and related equipment, such as printers and furniture, in the FY 1986 budget, and what is the estimated overall cost?

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Answer. $13.1 million has been requested in the FY 1986 budget for terminals and related Information Technology Systems equipment and $22 million for furniture. Overall costs for FY 1986 through FY 1990 are estimated at $136.2 million for terminals and related equipment.

Question. What plans do you have to train staff on the use of this new equipment, and how much will this training cost?

Answer. In concert with the Agencywide initiative to upgrade our systems and operations capacity, a Systems Modernization training plan has been developed. The goal is to produce timely, accurate, and quality training materials to meet the specific job training needs of our employees. We also are developing management training materials that emphasize the impact of automation and managing in a high technology environment. The technical and managerial training will take approximately 14 - 55 hours per employee (depending on the impact of the equipment on the job responsibilities), and will be delivered over the next 3 years at an approximate cost of $5,000,000.

Question. The General Accounting Office has recommended that you defer further consideration of the proposal to spend $16.2 million to purchase remaining computer terminals now leased from the Paradyne Corporation, until equipment failures have been reduced to a rate experienced by similar systems. What is the status of your plan to purchase computer terminals from the Paradyne Corporation?

Answer. We have no action underway, or proposed, to purchase the terminals that are currently leased from Paradyne.

Question. What use do you plan to make of the Paradyne equipment?

Answer. The existing Paradyne equipment does not have features which will meet the long-range terminal requirements for SSA. Paradyne terminal configurations have already been declared obsolete and will be disposed of after they are fully depreciated while those that are on lease will be returned to Paradyne.

Question. How can you be confident your Systems Modernization Plan will be carried through as plannned, given the problems experienced with the Paradyne case?

Answer As indicated in earlier questions, SSA has built in many safeguards to assure effective implementation of the Systems Modernization Plan.

LOW INCOME HOME ENERGY ASSISTANCE

Question. The formula for allocating energy assistance funds among the States is based on home energy expenditures by low income households, and the Department of Health and Human Services must collect data detailing information on home energy consumption such as the amount, cost, type of fuel used, and the number income levels of households assisted. Do the data collected by HHS show that the current level of energy assistance is sufficient, that the focus of the program is appropriate and that it serves those whose need is greatest?

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Answer. For several years, we have collected information from national surveys about the energy expenditures of low income households and the characteristics of LIHEAP recipient households. What we have seen is that recipient households tend to have lower incomes and higher energy costs than the average low income household. So, among the households which Congress identified as eligible for the program, the States seem to be reaching those with relatively higher proportions of their incomes going for heating costs. Since, after receipt of LIHEAP payments, those households are using about the same proportion of their income for heating as households around the maximum income eligibility level, we think the focus of the program is appropriate.

Question. HHS must issue new regulations to prevent waste, fraud, and abuse in the Low Income Home Energy Assistance Program. Is there evidence to suggest that the Low Income Home Energy Assistance Program has fallen victim to waste, fraud, and abuse, or that funds are not being dispensed effectively for the purposes Congress intended? What measures has HHS taken to insure that waste, fraud, and abuse do not occur?

Answer. The block grant statute requires that grantees perform an annual audit of their LIHEAP funds and provide a copy to the Secretary of HHS. The statute requires the Secretary to investigate complaints that a State is not using its funds in accordance with the law, and to undertake reviews of several States each year to determine whether funds are being spent in accordance with the law. Neither the audits we have received, nor the compliance reviews we have performed covering 26 States and 6 tribal grantees since FY 1982, have found evidence that LIHEAP has fallen victim to systematic waste, fraud and abuse, or that funds are not being dispensed effectively for the purposes Congress intended. In response to a directive in the Human Services Reauthorization Act of FY 1984, P.L. 98-558, we are developing regulations to help prevent waste, fraud and abuse.

HOMELESS PERSONS ON SSI

Question. It appears that the number of persons who are homeless is increasing. The poverty of these people is obvious. The SSI program serves needy aged, blind, or disabled persons. Is there research underway that would answer the question, how many homeless persons receive SSI, or are eligible for SSI?

Answer. We currently have no research underway that will answer either of these questions. The automated record system used in the SSI program does not capture information on homelessness. Special outreach efforts and operating procedures are in place to accomodate the needs and problems of the homeless in the context of participation in programs administered by SSA.

CHARACTERISTICS OF AFDC RECIPIENTS

Question. The latest published data available on characteristics of AFDC recipients is based on a March 1979 survey. Does HHS have more recent comparable data? If so, why hasn't it been released?

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Answer. Yes, we have much more recent data. Since October 1982, we have been gathering characteristics data during ongoing quality control reviews. While we have not released this data in the form of published tables, we have used it to respond to a number of requests from both government and the private sector. For example, the House Ways and Means Committee used it in its February 1985 publication entitled "Background Material and Data on Programs within the Jurisdiction of the Committee on Ways and Means." Also, we used it to provide CBS News with a profile of a "typical" AFDC recipient.

To fill the gap between the March 1979 survey and the first available data from our current system, the Office of Family Assistance conducted a special survey which used a national sample of quality control review records for May 1981 and May 1982. Data from this survey have been very widely used.

Question. Is HHS planning to continue the AFDC characteristics survey?

Answer. We plan to continue gathering characteristics data as part of the ongoing quality control reviews. We now have preliminary data for the period through September 1983. Our plans are to collate characteristics data every 6 months under this system, which will represent an improvement in timeliness over the biennial Recipient Characteristics Studies.

RESEARCH ON WORK PROGRAMS

Question. The 1981 Budget Reconciliation Act made major changes in the structure of work incentives and work programs in the AFDC program. Does HHS have underway research that would improve our knowledge about the labor supply behavior of low-income people?

Answer. Research Triangle Institute (RTI), under contract with SSA, studied the effects of the 1981 OBRA changes on the work effort of AFDC recipients. The final report was released in June 1984. RTI found that OBRA did not reduce either the work effort of working recipients who lost eligibility because of the reforms or the uptake of work by non-working recipients.

Currently, SSA is funding two demonstrations of urban saturation work programs. Grants have been awarded to California and Pennsylvania to evaluate the net impact of a work program in a city of at least 400,000 inhabitants. In these projects, in any given month, at least 75 percent of the eligible program participants will be actively involved in work programs. Among the outcomes which will be measured is the level of employment among participants. These projects are being operated in San Diego and Philadelphia from October 1984 through September 1987, subject to annual renewal.

The impact of the Department's work programs on the work effort of AFDC recipients is also being studied in several States by the Manpower Demonstration Research Corporation (MDRC), an independent research firm. In their preliminary impact analysis in San Diego, MDRC found that mandatory participation in job search or Community Work Experience increased employment and

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earnings among regular (single-parent) AFDC recipients. MDRC's reports on other sites have so far involved only process analysis, rather than a study of impacts of the programs.

PARADYNE CONTRACT

Question. Please give the Committee a complete run-down of the criticisms that were made of SSA's management of the Paradyne contract, and how the Agency has responded to each one. What actions were taken against the company and the individuals involved (both within the company and SSA)?

Answer. The principal criticisms of SSA's management of the Paradyne contract were:

--Inadequate checks and balances outside the Office of Systems to alert SSA/HHS officials to impending problems.

--Inadequate and uncoordinated acceptance testing.

--Inadequate and uncoordinated performance monitoring after acceptance.

Both the Department and SSA have taken actions to help eliminate these problems. The Department established an Information Resources Management (IRM) Advisory Board to foster the exchange of technical information, and to establish operational principles and strategies.

The Department also has been working through the President's Council on Integrity and Efficiency (PCIE) to develop and institutionalize engineering standards for integrated hardware/software systems, throughout the Federal Government in conjunction with the National Bureau of Standards. (Begun in 1984)

The Inspector General (IG) established a permanent onsite audit team at SSA headquarters to monitor the performance of systems development activities. (Begun in 1983)

The Office of the Assistant Secretary for Management and Budget (ASMB) maintains a list of all Departmental ADP contracts, and conducted a review of a representative sample of all of these contracts to ensure compliance with delegated authority. The program is to be turned over to the Inspector General for ongoing support by the IG's office. (First review completed in 1984)

The ASMB and staff review every SSA ADP procurement costing over $50,000 if sole-source, or $150,000 if competitive. The review has been extended in recent years to cover selected requests for proposals (RFP's) and proposed evaluations. (Increased efforts in 1983)

We have established a program of regular monthly meetings with Departmental officials and General Services Administration representatives for the purpose of reviewing procurement plans and actions. (Begun in 1984 on a regular basis)

We have established a Systems Acquisition Management Staff

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within the Office of Systems (20 people) to assist the Deputy Commissioner for Systems in establishing systems policies and procedures and monitoring adherence to those policies (e.g., clarity of specifications, feasibility of requirements and technical approach and evaluation of acceptance criteria). (Organizational change in late 1984)

In addition, in March 1985, the Secretary approved the elevation in the organizational hierarchy of the Division of Grants and Contracts Management, outside the purview of the Office of Systems. The head of the organization will report directly to the Associate Commissioner for Management, Budget and Personnel. We are also reviewing the staffing of that function to assure that adequate resources are available to carry it out.

On March 12, 1985 the Assistant Secretary for Management and Budget, HHS, sent to the Paradyne Corporation a notice of proposed debarment from all Federal Government contracting. The proposed action is based on an internal HHS task force report which concluded that Paradyne substantially misrepresented the status and availability of systems communication equipment during the proposal stage of the procurement process. The Paradyne Corporation has opposed our legal basis for debarment and has requested that the proposed debarment be withdrawn. The Department is curently reviewing the written submission which Paradyne submitted in opposition to the proposed debarment.

If the Paradyne Corporation is debarred, it will be precluded from contracting with any Federal agency for up to 3 years, unless the head of the affected agency determines that there is a compelling reason to do business with the company. If the decision is made to debar, Paradyne Corporation can seek judicial review of the debarment.

No actions have been taken against SSA employees who were involved in the evaluation and negotiation of the procurement because no wrongdoing by them has been shown at this time. The internal HHS task force concluded that the SSA officials appropriately relied upon the representation contained in the Paradyne proposal.

SYSTEMS MODERNIZATION PLAN

Question. Originally, the Systems Modernization Plan was estimated to cost close to $500 million. Does the Agency still stand behind this estimate? If not, what is it now and why has it changed?

Answer. The original Systems Modernization Plan (SMP) was published in February 1982 with an estimated 5-year cost of $478.6 million. As the original plan indicated, "This is a dynamic plan which covers a 5-year period. It will be updated annually. By necessity, the first year under the plan will be much more detailed than the fifth--and it will always be that way. Five years from now we want to be working on the first year of a new 5-year plan rather than the last year of an old 5-year plan." SSA's intent was, and is, to update the plan annually to reflect changes in the environment in which it was, and is, being executed.

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The current 1985 update to the SMP, published in January 1985, shows an actual and projected cost for the period of March 1982 through September 1989 of $863.1 million. This update includes $322.4 million for the recently established Administrative/Management Information Engineering Program for the 5-year period FY 1985 through FY 1989; and $23.8 million for the System Operation Management Program which were not part of the original SMP. The remaining $516.9 million in the current update compare favorably to the original plan, but cover an additional 2 1/2-year planning horizon beyond the original SMP.

TAXATION OF BENEFITS

Question. Has your Agency notified all Social Security recipients of the amount of benefits they received in 1984 so that they can determine if they must pay tax on them?

Answer. Yes, statements were mailed between January 5 and January 29.

Question. How much does this provision cost to administer?

Answer. SSA's budget includes estimates of $65.7 million in FY 1985 and $41.2 million in FY 1986 to administer taxation of benefits. The FY 1985 estimate is higher than the estimate for FY 1986 because we assumed that inquiries in the first year of implementation would be significantly higher than in subsequent years. However, based on experience so far in FY 1985, it appears that the major workloads (i.e., inquiries) are not coming in as heavily as expected, and actual costs will be lower than budgeted.

Question. Describe what administrative problems you have encountered in implementing this provision?

Answer. In general, we encountered few difficulties and used fewer resources than we had expected in implementing this provision. Legislation was enacted on April 20, 1983 and the new system to capture the detailed data had to go into operation in December. This left about 7 months for us to determine what data to record, how to record it and how to produce the roughly 40 million statements. We had to identify and resolve problems, both within SSA and with the Internal Revenue Service.

Since our recordkeeping for benefit payments does not conform to that required for tax purposes, we had to create a new record. We did so through the Payment History Update System or PHUS. we think we did a good job in that the statements were issued timely with a minimum of problems.

There are approximately 250,000 cases where payment of Social Security title II benefits is actually made by the Railroad Retirement Board (RRB). We concluded that the literal language of section 6050F of the Internal Revenue Code required us to issue statements of such benefits. Therefore, we arranged with RRB for that agency to give us tapes of title II payments made by RRB so we could issue statements. The operation was not completely satisfactory because some data received from RRB was incomplete; we are working with RRB to resolve these problems.

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An ongoing problem may be the short amount of time alloted for the preparation of the statements. The statement is to cover the entire calendar year and must be furnished to the taxpayer no later than January 31 of the following year. We found that we could not wait until the year had ended to start production of the statements. In the vast majority of cases, the last transaction in December was the payment on the third, so we closed our books just after that date, and prepared tapes from which our printing contractor could prepare the statements. As a result of this advance delivery, the contractor could begin the actual printing in the first week of January. We subsequently prepared a supplemental file of roughly 500,000 accounts with some transactions after December 3. This resulted in some people receiving two statements, but we saw no alternative.

We also experienced administrative problems with the approximately 220,000 nonresident aliens. In addition to furnishing statements of benefits paid, we had to withhold tax. While the prescribed rate was 30 percent of one-half the monthly benefit, a different rate applied if a tax treaty provided otherwise. In the case of Canada, we initially withheld at the statutory rate; however, reinterpretation of a treaty between the two countries resulted in a rate of withholding of only 15 percent. Finally, the ratification of a renegotiated treaty resulted in an exemption for Canadian residents.

There was uncertainty over the status of Puerto Rico, the Virgin Islands, Guam, and American Samoa. For Social Security purposes, these areas are part of the United States and their inhabitants are citizens or nationals of the United States. For income tax purposes, though, different rules apply. We finally clarified the status of residents of Puerto Rico, the Virgin Islands and Guam.

We think we did a good job in that statements were issued timely with minimal problems.

Question. Describe what the public's reaction has been so far?

Answer. In the first 3 months of 1985, we received about 1 million inquiries about taxation and the Form SSA-1099, Statement of Benefits. Since we estimated that we could receive as many as 9 million inquiries, public reaction could be described as mild. We believe this small percentage was due to extensive publicity and the clarity of the form. We designed the form and the public information campaign in anticipation of the beneficiary inquiries. We worked with the Internal Revenue Service to develop a worksheet which a beneficiary could use to determine whether any benefits should be included in taxable income. Most beneficiaries, after completing the worksheet and determining that their benefits would not be taxed, saw no reason to inquire further. The inquiries received were mostly of the nature anticipated and could be handled solely on benefit information printed on the form.

SYSTEMS AND PROCEDURAL IMPROVEMENTS

Question. Please give us specific examples of procedural or systems changes that have been made so far, or are about to be

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made, that have either saved money or improved service to the public as a result of the systems modernization effort.

Answer. Some examples of systems changes or procedural improvements which have been implemented and which have reduced administrative resource requirements and/or improved service to the public are:

- o Field offices now process about 25 percent of all claims for retirement and survivors benefits from application to receipt of the first check within about 1 week, compared to about 2 weeks under the old process.
- o Field offices may now enter Social Security number applications directly into the system and thereby shorten the time from application to receipt of a card from 4 - 6 weeks to an average of 11 days.
- o More efficient data processing procedures now allow quicker payment of increases in benefits due to additional earnings.
- o Improvements in SSA's master beneficiary record processing permit us to make changes in this system much faster than ever before.
- o SSA's online data base was expanded to allow field offices to provide benefit estimates for persons age 60 or older immediately.
- o Conversion of data from tape to direct access disk storage has reduced tape usage and tape mounts and has enabled us to put data online to field offices.
- o The telecommunications network capacity has been increased, thereby eliminating a backlog of messages, reducing inquiry response time, and increasing the number of transactions which can be handled.
- o The latest cost-of-living adjustment benefit increase was processed in 2 days instead of 2 weeks.

SOCIAL SECURITY COST OF LIVING ADJUSTMENTS

Question. What would the savings be over the next 3 to 5 years if the January 1986 Social Security COLA were frozen?S-131

Answer. The FY 1986 budget assumes a 4.1 percent cost-of-living adjustment for Social Security benefits payable in January 1986. Based on the budget assumptions, the estimated amounts of reduction in benefit payments from the old-age, survivors, and disability insurance (OASDI) programs resulting from elimination of that benefit increase would be as follows:

FY 1986.....	$5.8 billion
FY 1987.....	$7.9 billion
FY 1988.....	$8.0 billion
FY 1989.....	$8.1 billion
FY 1990.....	$8.0 billion

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The savings for FY 1986 are smaller than in later years because the COLA is effective for only 9 months (January - September 1986) rather than for the full fiscal year.

The reductions in benefit payments shown above would be offset slightly by reductions in income from the taxation of OASDI benefits. In addition, increases would occur in the costs of other programs--for example, Supplemental Security Income (SSI) and Medicare--assuming that those programs were not changed under the proposal.

Question. Under what circumstances would the Administration support some form of constraint on the COLA's?

Answer. As you know, the President has stated that he will not propose any change that would cut Social Security benefits for current or future beneficiaries.

DIRECT DEPOSIT

Question. Last year SSA and Treasury were criticized for attempting to recover overpayments made to recipients directly from their back accounts without warning. Are you still engaging in this process?

Answer. Whenever SSA receives information that a payment has been credited to a beneficiary's bank account by direct deposit for months after his or her death, we notify Treasury. Treasury notifies the financial institution involved that the payment was made in error and requests that an amount equal to the erroneous payment be returned to the Government.

Last year SSA worked with the Treasury, which is the Department responsible for direct deposit procedures, regarding Treasury's reclamation procedure in direct deposit cases. On December 17, 1984, the Department of Treasury published a regulation in the Federal Register which requires financial institutions to send a notice to the current address(es) of the account owner(s) whenever the financial institution intends to take action against an account for recovery of an erroneous direct deposit payment. The effective date of the Treasury regulation is April 21, 1985.

Question. If so, what is your basis for doing so?

Answer. Erroneous payments credited to the account of a beneficiary after his or her death are not treated as overpayments under Section 204 of the Social Security Act. That section applies to situations where more than the correct amount has been paid to a person where that person is the recipient for whom the payment was intended.

Question. As a minimum measure, shouldn't the holder of the account always be notified either beforehand or simultaneously that the recovery is being made from his or her account?

Answer. Under regulation effective April 21, 1985, financial institutions are required to send to the account holder's address a notice about action taken to resolve an erroneous payment.

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Question. The Systems Modernization Plan was launched in 1981 to modernize the automated systems of the Social Security Administration. Would you describe for the Committee where your Agency now stands in implementing the plan.

Answer. The Agency is now 3 years into implementation of the SMP which began in early 1982. SSA has completed the "Survival" and "Transition" phases, scheduled over the first 3 years, and is now entering the "State-of-the-Art" phase in which we plan to apply the most modern technology available to our systems. The "Survival" phase laid a solid foundation for achieving our ultimate systems modernization goal. New computers and automated tools for computer operations were installed, eliminating large backlogs of work which had accumulated when our systems were inadequate. As originally planned, the "Transition" phase has addressed both the tactical and strategic systems needs of SSA by targeting a few critical systems for immediate modernization (e.g., the Claims Modernization Project) and by proceeding with the comprehensive design and development of the new software systems for SSA (referred to as Logical Application Groups or LAGS). SSA is also modernizing its data base and telecommunications capabilities to support the future modernized system. Most recently, SSA has begun to give priority to the modernization of its administrative and management information systems. SSA is also now studying long-range demands such as distributed data processing which has potential value for improved workload distribution and disaster avoidance. As I explained earlier, the SMP has already resulted in a number of systems improvements, delivering better service to the public and automating heavily manual tasks.

Question. How much assurance can you give this Committee - based on your progress to date - that this effort will be any more successful than the previous "Advanced Systems Planning" effort was in the late 1970's?

Answer. Accomplishments, to date, are significant in virtually all systems areas - software engineering, data base integration, telecommunications improvements, capacity upgrades, system operations management and administrative/management information engineering. We have already experienced significant improvements in service to the public, and the success to date already far exceeds that of the earlier Advanced Systems Planning effort. SSA's top staff is totally committed to the successful completion of all the goals and objectives of this effort.

Question. How much have you spent on this plan so far and how much "concrete" action has been taken?

Answer. For the period of March 1982 through September 1984 the Agency has spent $101.3 million on SMP initiatives. "Concrete" actions have been taken:

--Initial implementation of a Software Engineering Technology (SET), including staff training, for developing, documenting, managing and maintaining computer software.

--A "top-down analysis" of SSA's business processes and

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programmatic requirements including an evaluation of existing software and its compatibility with a modern information processing architecture.

--Initial redesign of the title II claims process under the Claims Modernization Project currently being piloted in two field offices.

--Acquisition of contractor services for redesign of SSA's Annual Wage Reporting (AWR) process.

--Implementation of an interim debt management system to improve the control and processing of title II and XVI overpayments.

--Acquisition of contractor services for design and development of an integrated national debt management system.

--Improvements to the Enumeration System that now issues Social Security cards in 11 days compared to 6 weeks processing time formerly.

--Cost-of-living benefit rate increase operation now processed in 2 days compared to 11 days processing time formerly.

--Obsolete mainframes in the National Computer Center replaced, eliminating programmatic and telecommunications backlogs.

--Installed 780 billion bytes of disk equipment; converted master beneficiary, enumeration, and title XVI master files from tape to disk; eliminated about 500,000 tape mounts/dismounts each year.

--Automatic Earnings Recomputation Operations backlog eliminated, and automation rate increased by 13 percent over past year.

--Postentitlement actions currently processed daily compared to 2-3 times per week formerly; overall run time reduced from 180 hours per week to 70 hours.

--Current Annual Wage Reporting System processing timeframes reduced to 8 months from 15 months.

--Replaced aging case control system in the Program Service Centers with bar code scanners.

--Implemented automated job scheduling in the National Computer Center.

--Completed preparation of acquisition documentation, obtained HHS and GSA approval to acquire contractor services in FY 1985 for functional requirements development for modernization of SSA's program benefit, inquiry/response, quality assurance and data exchange software application architecture areas.

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--Completed general design and preparation of acquisition documentation and obtained HHS and GSA approval to acquire equipment to implement the SSA Data Communications Utility.

--Established the Office of Information Systems (OIS) to develop and oversee the modernization of SSA's management information systems. Initial accomplishment has been the development of an Administrative/Management Information Engineering Systems Modernization Plan which is being integrated with the original Systems Modernization Plan.

--Established a Systems Acquisition Management Staff in the immediate Office of the Deputy Commissioner for Systems to exercise tight controls and review of systems procurements.

--Acquired Department of Agriculture Graduate School services to improve employee skills essential to support SMP activities through a variety of training programs. To date, over 8,600 training experiences have been provided by USDA.

EFFECT OF SOCIAL SECURITY EXPENDITURES ON THE BUDGET DEFICIT

Question. There has been a lot of confusion about whether or not Social Security affects the Federal budget. Would you explain how Social Security relates to the budget and whether or not a reduction in Social Security expenditures would reduce the budget deficit?

Answer. Under current law, Social Security income and outlays will be included in the unified budget through FY 1992, then excluded in FY 1993 and thereafter. Operating surpluses in Social Security until 1993 would help to reduce the Federal budget deficit, while deficits in Social Security would exacerbate the Federal budget problem. Thus, any reduction in Social Security expenditures, such as a freeze in the cost-of-living adjustment, without a corresponding decrease in Social Security taxes, would reduce the unified budget deficit.

However, Social Security trust fund surpluses cannot be used to buy more weapons, increase agricultural subsidies, or increase welfare. They can be used only for Social Security purposes--that is, to pay Social Security benefits and administrative expenses, or to be invested to increase trust fund income.

FINANCIAL CONDITION OF THE SOCIAL SECURITY SYSTEM

Question. The Social Security Amendments of 1983 were enacted in order to improve the ailing financial condition of the system? Is it true that if the country were to fall into another recession during the next few years, financial problems could re-emerge?

Answer. The 1985 Annual Report of the Board of Trustees of the Old-Age, Survivors, and Disability Insurance (OASDI) trust funds was transmitted to the Congress on March 28, 1985. Based on the assumptions used to prepare the estimates shown in that report, the assets of the OASDI funds will remain fairly low, relative to annual outgo, through about 1987, after which they will increase rapidly. Thus, if a severe recession were to occur

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before the end of 1987, it could cause financial problems, but that does not seem likely at this time.

The pessimistic (alternative III) assumptions shown in the 1985 Trustees Report include two recessions during the rest of the 1980's. Based on those assumptions, the Disability Insurance (DI) trust fund would become exhausted by the end of 1987, but the assets of the Old-Age and Survivors Insurance (OASI) trust fund would be more than sufficient to make up the shortfall, which could be done by means of a reallocation of contribution rates between OASI and DI. Such reallocations have occurred often in the past, most recently in 1983 and in 1980.

Question. Please provide the Committee with the latest outlook, i.e., a narrative prognosis, of the financial condition of the Social Security system.

Answer. The 1985 Annual Report of the Board of Trustees of the Old-Age, Survivors, and Disability Insurance (OASDI) trust funds was transmitted to the Congress on March 28, 1985. The "Conclusion" of that report provides an excellent summary of the OASDI program's current financial condition. A copy of the report has been provided to the Committee.

Question. What institutions or Social Security experts have been saying that the system is not financially secure, and what are they basing their conclusions on?

Answer. The most widely accepted analysis of the financial condition of OASDI is contained in the annual Trustees Report. The 1985 report indicates that the OASDI program is in generally good financial condition. Some have questioned the assumptions used to prepare estimates for the annual Trustees Reports, saying that they may be too optimistic, but others have said the opposite. In the past, some analysts have emphasized the possibility of financial problems in the event of a severe recession before 1987, but that appears to be less likely with each passing year. Other analysts have pointed out the financial problems likely to affect the Hospital Insurance (HI) portion of Medicare, but that is not directly related to OASDI.

LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

Question. The re-authorized Low Income Home Energy Assistance Program requires more extensive data collection by HHS and more detailed reports for the States. Will the new data the Low Income Home Energy Assistance Program is required to collect permit more efficient monitoring of the program? What steps is HHS taking to insure the quality of its data?

Answer. Section 607 of the Human Services Reauthorization Act, P.L. 98-558, added two data requirements to those already present in the LIHEAP statute. HHS must collect information about the amounts of fuels used by low income households, as well as the types and costs. We must also collect information about the number and income levels of assisted households with elderly or handicapped members, as well as the number and income levels of all households assisted. Our reports to the Congress for the last 2 years have included information of this kind. In line with our

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policy to keep block grant reporting requirements to a minimum, we have relied largely on results of national surveys performed by the Department of Energy and the Bureau of the Census to develop data on the energy costs and other characteristics of low income households and LIHEAP recipients. We believe that this method assures that the data reported to the Congress are of high quality.

AFDC PAYMENT ERROR RATES

Question. The Tax Equity and Fiscal Responsibility Act of 1982 requires States to move from the FY 1983 maximum AFDC payment error rate of 4 percent established by the Michel Amendment to a 3 percent maximum AFDC error rate for FY 1984 and years thereafter. Has the Social Security Administration imposed sanctions against the States that failed to meet their FY 1981 error rate targets?

Answer. The Secretary recently announced her decision on requests from the 28 States which sought waivers of the FY 1981 disallowances. Six of the 28 States received waivers of their disallowances. The remaining 22 States are subject to disallowances for their excess erroneous expenditures.

Disallowance letters will be sent to States shortly advising them of the actual disallowance amount. These letters also advise them of the administrative appeal process which is available to the States.

Question. Why haven't FY 1982 error rate data been released?

Answer. We believe it would be unfair to the States to release the FY 1982 error rates until decisions are made and information is released on the States' FY 1981 waiver requests. Therefore, we plan to release the FY 1982 error rates soon after the FY 1981 waiver decisions are presented to the States.

Question. How many States have failed to meet the FY 1982 error rate targets?

Answer. As you know, 28 States failed to meet their FY 1981 error rate targets. Unofficial estimates indicate that a similar number of States may not reach their targets for FY 1982.

Question. How much are fiscal sanctions estimated to be for fiscal years 1981, 1982, 1983, 1984, and 1985?

Answer. The potential liabilities for the subject fiscal years have been estimated as follows:

FY 1981.....	$ 74,000,000
FY 1982.....	$ 99,000,000
FY 1983.....	$180,000,000
FY 1984.....	$234,000,000
FY 1985.....	$220,000,000

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SECTION 1619 PROGRAM

Question. Social Security Disability Benefits Reform Act of 1984 (Public Law 98-460) includes a provision that extends Section 1619 of the Social Security Act through June 30, 1987, retroactive to January 1, 1984. The purpose of Section 1619 is to encourage disabled SSI recipients to attempt to return to work.

How many persons are participating in the Section 1619 program?

Answer. Our records show that as of August 1984, there were approximately 7,500 persons benefiting from Section 1619.

Question. Is the Social Security Administration in favor of making the Section 1619 program permanent?

Answer. As you know, the provisions of Section 1619 were extended through June 30, 1987, by P.L. 98-460, the Social Security Disability Benefits Reform Act of 1984, enacted October 9, 1984. The purpose of this extension was to allow time for further study of the effects of the Section 1619 provisions. Together with the Health Care Financing Administration and State agencies administering the Medicaid program, SSA currently is studying the effects as required by the Ways and Means Committee report (No. 98-618) on the bill which extended the provisions. SSA will report the results of the study to the Congress in mid-1986. The report will describe the characteristics of the individuals benefiting from Section 1619, the effects of the section on work efforts, and the types and costs of health services used under continued Medicaid eligibility. Further legislative action on Section 1619 should allow for consideration of the study findings.

CHILD SUPPORT ENFORCEMENT

Question. The Child Support Enforcement Amendments of 1984 and the Deficit Reduction Act of 1984 made major changes in the Child Support Enforcement program. How do the States view the recent changes in the Child Support Enforcement program? What are their concerns?

Answer. How the States view the changes as a result of last summer's legislation varies depending on the particular provision of the new law and the State. Also, who is meant by "the State" must be considered as the perspective of a IV-D Director may differ from that of a State legislator or a IV-A Director, for example. The perspective of each will effect their particular viewpoint and concerns. In general, however, the States view favorably the mandatory enforcement techniques. State response to the new incentive formula has been mixed, but favorable overall because of the recognition of non-AFDC collections.

States have been most vocal in their opposition to the $50 disregard of child support provision of the Deficit Reduction Act of 1984. As a result of this provision, the first $50 in current child support collected each month would go directly to the family and not be counted as income for purposes of AFDC eligibility. This directly reduces the money which formerly would have gone to the States to reduce their welfare costs. The loss of these funds is the predominant concern of the States in the changes in the area of child support.

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Question. Do States foresee their administrative costs increasing? To what extent?

Answer. States project their net expenditures to rise by $27 million in FY 1985 and by another $25 million in FY 1986. This represents an approximate 11 percent increase per year, primarily to put in place the administrative structure to support the various amendments of the legislation. Once the amendments become fully implemented, the rate of growth of expenditures in the out years will be slowed due to the cost effective nature of these amendments.

Question. Throughout its history the Child Support Enforcement program has been a net fiscal gain for the States and a cost to the Federal Government. Before the 1984 Amendments, analysts maintained that the financing system of the Child Support Enforcement program gave the States little incentive to run cost effective programs. Will the program continue to be a net fiscal gain for the States? How will the Federal Government fare?

Answer. Overall savings from this program to both the State and Federal Governments has been $1.4 billion through FY 1984. States have realized a $2.2 billion savings in that time, while the Federal Government has lost $0.8 billion. Although the program has realized an overall savings each year through FY 1984, the impact of the $50 disregard causes the program to suffer projected losses beginning in FY 1985. For comparative purposes, the program gained $286 million in FY 1984 and projects a loss of $41 million in FY 1985.

State share of savings has always been positive. Although the $50 disregard causes State share of savings to drop by a projected $132 million in FY 1985, States still realize a projected $240 million in that year. That share is expected to rise to $270 million in FY 1986.

Federal share of savings has never been positive. The Federal share of savings goes from a negative $85 million in FY 1984 to a negative $281 million in FY 1985 as a result of the $50 disregard. That figure rises to a projected negative $332 million in FY 1986.

Until the Child Support Enforcement Amendments of 1984 were passed, Federal funding was linked solely to expenditures regardless of how effective the State program was that those funds supported. With passage of the new legislation, a new incentive structure has been put in place that encourages cost effective administration and collection for both AFDC and non-AFDC cases. In addition, Federal financial participation is gradually reduced in the out years after proven cost effective collection techniques have become mandatory. All of these measures will mean that the program will become progressively more cost effective in its returns to both the Federal and State Governments.

Question. Are the new rules expected to make State administrative costs more uniform and the programs more efficient?

Answer. Variations in administrative costs from State to State will always exist. This is inherent in the system due to variations in administrative structures between the States, differing salary levels from State to State, and other State particulars. Opportunities do exist, however, for more efficient programs through commitment and good management. Commitment to the program and leadership on the part of human service agency

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heads and elected officials at all levels of government can lead to a more effective and efficient program.

The Child Support Enforcement Amendments of 1984 will significantly improve the efficiency and effectiveness of the program. The mandatory State practices, revised incentive system, audit provisions, and gradual reduction in Federal financial participation in the late 1980's emphasize performance.

Question. The Deficit Reduction Act of 1984 requires that the first $50 collected on behalf of an AFDC child be paid to the family as an addition to their AFDC grant. Who is paying for the $50 child support disregard? The States? The Federal Government?

Answer. Payment of the $50 disregard is coming from both the Federal and State Governments in the form of a reduction in the flow of funds back to government when current child support collections are secured on behalf of AFDC recipients. The Federal share of the costs related to the $50 disregard is $142 million in FY 1985 and $151 million in FY 1986. The State share of the costs is $113 million in FY 1985 and $133 million in FY 1986.

Question. What impact does the $50 child support disregard have on State costs? Federal costs?

Answer. Overall the program will lose a projected $255 million in FY 1985 and $284 million in FY 1986. Of that loss, the Federal Government's share is $142 million in FY 1985 and $151 million in FY 1986. The States' share of the loss is projected at $113 million in FY 1985 and $133 million in FY 1986.

The $50 disregard has not been in force long enough to adequately project its full impact. For example, the provision substantially complicates the administration of the AFDC program because the State must pay to the family the $50 of current child support and keep track of when the family receives it in order to appropriately disregard this money for AFDC payment purposes.

Question. What impact does the $50 child support disregard have on the Child Support Enforcement program? What impact does the provision have on the AFDC program?

Answer. Overall the program will lose a projected $255 million in FY 1985 and $284 million in FY 1986. Of that loss, the Federal Government's share is $142 million in FY 1985 and $151 million in FY 1986. The States' share of the loss is projected at $113 million in FY 1985 and $133 million in FY 1986.

The $50 disregard has not been in force long enough to adequately project its full impact. It is still too early to assess the effect of the additional administrative complexity, the behavioral impact on current or potential AFDC recipients, or a number of other possible ramifications of this legislation.

Question. The Child Support Enforcement Amendments of 1984 requires that States charge an application fee for non-AFDC cases not to exceed $25. How many States pay the fee out of State funds?

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Answer. The mandatory application fee (up to $25) for non-AFDC services provision of the Child Support Enforcement Amendments of 1984 is not effective until October 1, 1985. States are still implementing this provision.

Question. How many States recover the fee from the custodial parent? The noncustodial parent?

Answer. The non-AFDC application fee provision is not effective until October 1, 1985. We do not have a good indication at this time as to which States, if any, plan to recover the fee from the custodial parent or the non-custodial parent.

Question. Under the new incentive funding formula, a State may be able to retain up to 10 percent of its AFDC and non-AFDC collections, depending on the ratio of its administrative costs to collections for both AFDC and non-AFDC families. Do you think that by emphasizing cost effectiveness the new formula will encourage States to pursue the cases that are relatively easy to enforce and ignore the more difficult cases?

Answer. OCSE regulations on case management and prioritization offer States a means of enhancing the effectiveness and efficiency of their operations by improving the management of cases. Under these regulations, the State must ensure that no program services (e.g., establishing paternity) required to be performed under the IV-D State plan are systematically excluded by the prioritization system. In addition, a State cannot neglect or ignore certain cases or classes of cases.

Proposed revisions to the OCSE audit regulations published in the Federal Register on October 5, 1984, require the States to meet State plan related functional audit criteria in order to be found to have an effective IV-D program and to avoid imposition of the penalty. Under these regulations, the States must use the procedures required by functional audit criteria, such as establishing support obligations, establishing paternity, enforcement of support obligations, and cooperation with other States, in 75 percent of the cases reviewed for each criteria. Unless a case was closed or improperly referred by the IV-A agency, it will be reviewed under criteria related to any functions or services (e.g., establishment of paternity) that, based on the case record and any statewide guidelines, were necessary during the audit period. We plan to issue final audit regulations on this subject in the near future.

Question. Will the new incentive formula undermine State and local efforts to establish paternity since such cases are usually more difficult?

Answer. No. The incentive formula, effective October 1, 1985, permits States to deduct laboratory costs related to the establishment of paternity from their administrative costs used in calculating incentive payments. More importantly, establishing paternity early has a potential long-term payoff of child support collections over many years, a benefit which surely exceeds any reasonable initial outlays. And, through sound interviewing techniques, judicious use of scientific testing and plain good management, costs of establishing paternity can be kept within reasonable bounds. Finally, our regulations ensure that child support cases needing paternity establishment are given appropriate emphasis when States are prioritizing their caseloads.

The findings of a study on the costs and benefits of paternity establishment indicate that paternity cases can be processed cost-effective-

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ly in a reasonable period of time. In two study sites it was discovered that all costs associated with establishing and enforcing obligations for all paternity cases regardless of outcome could be recovered within three years.

Question. What impact will the new formula have in States and localities with high proportions of births outside of marriage?

Answer. Births out of wedlock should not be a significant factor in the impact of the new incentive formula on the States. The new Federal law permits States two significant avenues for reducing the cost impact of establishing paternity. States may deduct from their administrative expenses, for the purpose of calculating incentives, the cost of laboratory tests related to paternity establishment. These scientific tests are reportedly a significant part of the administrative costs associated with paternity establishment. In addition, another significant expense in this area, court costs may be reduced if the State opts to use its expedited legal process for establishing paternity.

Question. Paternity establishment is one of the primary functions of the Child Support Enforcement program. Is it true that paternity establishment technology is not as conclusive for non-white persons, particularly blacks, as it is for whites?

Answer. Paternity establishment technology has progressed to the point where paternity testing itself is generating enough data to provide gene frequencies for Blacks and Hispanic Americans. While paternity establishment technology was not as conclusive for non-whites in the past, vast improvement in laboratory techniques, the availability of reagents, and numbers of tests have narrowed the gap.

Question. Is it true that in relation to other program accomplishments, paternity establishment has not kept pace?

Answer. Under the Child Support Enforcement program, States have established over 1.2 million paternities. In the last 5 years, paternity establishment increased by 52 percent. Establishment of paternity was accomplished in a record high 219,360 cases in FY 1984, a 5.3 percent increase over FY 1983.

Question. The Child Support Enforcement Amendments of 1984 authorized an appropriation of $7 million in fiscal year 1985, $12 million in fiscal year 1986, and $15 million in fiscal year 1987 and years thereafter to be used by the Secretary to fund special projects developed by States to improve child support collections in interstate cases. What States have received Interstate Enforcement Project grants?

Answer. At this time, we have awarded none of these project grants, but we have received nine applications involving a total request of $4.3 million. We are in the process of negotiating with the States that submitted the five proposals in the first round in order to make their projects fundable. We expect to make the first awards soon. We are preparing to review another four proposals that were submitted March 29, 1985, and a third and final round of proposals will be forthcoming before the end of FY 1985.

Question. Please describe some of the more innovative approaches.

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Answer. Of the five applications received in the first of three FY 1985 review cycles, four involved computerization of the interstate process. The general idea of these four applications is to match records of various States for enforcement purposes and track and monitor the progress of interstate cases. Another innovative idea involved the use of video and teleconferencing to prepare and transmit evidence in interstate paternity establishment cases, thus saving time and costs. We expect more new approaches to be suggested in later project grant applications.

Question. The Federal Income Tax Refund Offset program increased collections in each of its three years of operation. Are collections expected to continue to increase?

Answer. We still lack sufficient experience in this area to give an answer that is more than speculation. However, based on the year-to-year trend thus far in both cases submitted for offset and offsets ultimately effected, the outlook for tax year 1984 is favorable.

Collections amounted to $168 million for tax year 1981, $175 million for tax year 1982, and $206 million for tax year 1983. However, it should be noted that the average offset per case has decreased from $614 in tax year 1981, to $517 in tax year 1982 and finally to $500 in tax year 1983.

Question. Is there evidence to support the premise that an absent parent who has had his or her refund intercepted changes his or her filing status the next year so as not to receive a refund? In other words, how many persons have their refunds intercepted more than once?

Answer. The IRS performed a study in October 1983 to determine whether any relationship existed between the tax offset program and income tax filing patterns. As a result of the study, the IRS and OCSE concurred that the report was inconclusive as to the effects the offset program has on tax compliance patterns and that further study was warranted.

Question. The Federal Income Tax Refund Offset program has reduced its operational costs per case from $17.00 in 1982 to $11.00 in 1983 and to $3.20 in 1984. How was the IRS able to reduce its operational costs per case to such a low level so quickly?

Answer. The IRS reduced its operational costs per case to such a low level so quickly because of a changeover from a predominately manual operation in 1982 to the current automated operation.

Question. What is the cost per case expected to be in 1985?

Answer. The cost per case for 1985 will be the same as it was in 1984, $3.20 per case.

Question. In 1983 the Bureau of the Census published a report on Child Support and Alimony using 1981 data. Does HHS know if the Bureau of the Census is planning to update that report?

Answer. OCSE sponsored a Bureau of Census Survey on Child Support and Alimony as part of the Current Population Survey in April of 1984. Data from this survey should be available in the summer of 1985.

Question. The Deficit Reduction Act of 1984 (Public Law 98-369) requires that the first $50 of child support collected on behalf of an AFDC

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family in any month be paid to the family without reducing the amount of the family's AFDC payment. What effect will this provision have on the AFDC program?

Answer. It is too early to assess the full impact of the $50 child support disregard. From a programmatic perspective, the Administration supports the view that all income and resources available to a family should be counted to meet basic needs. Furthermore, the provision substantially complicates the administration of the AFDC program because the State must pay to the family the $50 of child support and keep track of when the family receives it in order to appropriately disregard this money.

Question. What effect will it have on the Child Support Enforcement program?

Answer. Overall the program will lose a projected $255 million in FY 1985 and $284 million in FY 1986. Of that loss, the Federal Government's share is $142 million in FY 1985 and $151 million in FY 1986. The States' share of the loss is projected at $113 million in FY 1985 and $133 million in FY 1986.

Question. The Child Support Enforcement Amendments of 1984 (Public Law 98-378) made substantial changes to the nine year old Child Support Enforcement program. What provisions were to take effect on October 1, 1984?

Answer. Several provisions of P.L. 98-378 were effective October 1, 1984. The 90 percent Federal funding available for planning, design, development, installation, or enhancement of automated data processing systems is explicitly made available to include, at State option, development and improvement of the income withholding and other mandatory procedures through the monitoring of child support payments, maintaining accurate payment records, and providing notification to officials about arrearages. In addition, the 90 percent Federal funding is extended to the acquisition of computer hardware.

Also effective October 1, 1984, was the provision requiring the States to transfer automatically to non-AFDC status, AFDC recipients whose eligibility is terminated, without requiring application or payment of an application fee for IV-D services. This provision ensures continued support. Services must be provided in these cases on the same basis and under the same conditions as in other non-AFDC cases.

Other provisions which took effect October 1, 1984, are the availability of incentive payments to the States for the $50 per month of collections going directly to the AFDC family; the special project grants available to States to promote improvements in interstate enforcement; and child support enforcement for certain children in foster care.

Question. Were they implemented?

Answer. The States are required to implement the provisions of the new law in accordance with the relevant effective dates. State programs will be audited to determine compliance with the provisions effective October 1, 1984. A Notice of Proposed Rulemaking on the provisions of P.L. 98-378, including those effective October 1, 1984, was published September 19, 1984, in the Federal Register. Final regulations on these provisions should be published shortly.

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Expansion of 90 percent funding was authorized effective October 1, 1984 for automated systems to include monitoring of support payments, maintaining accurate records regarding support payments, notifying officials about arrearages that occur, and acquisition of computer herdware. In FY 1985, we estimate $25 million to be expended at the 90 percent level for systems enhancements.

In the case of the special project grants for interstate child support enforcement, two announcements about the availability of grants have been published in the Federal Register. Five applications were received in the first cycle of the process and four were received in the second cycle on March 29, 1985. We expect to utilize all $7 millior of the funds appropriated for this purpose in FY 1985.

Question. What provisions are scheduled to take effect this year?

Answer. Most of the provisions of the Child Support Enforcement Amendments of 1984 have an effective date of October 1, 1985. States are required to have laws and procedures for wage withholding, expedited legal processes, State income tax refund offset, imposition of liens, establishment of paternity until a child's 18th birthday, posting of securities or bonds, and reporting to consumer credit agencies.

The effective date of these enforcement techniques may extend beyond October 1, 1985 if State legislative action is necessary for the State to comply with the Federal law. If the Secretary determines that State legislation is required in order for the State to comply with the Federal requirements, a delay in implementation may be approved. All States, however, must have the necessary statutes and procedures in effect three months after the first State legislature session which ends on or after October 1, 1985. The revised incentive payment formula based on performance and expanded to non-AFDC cases is effective October 1, 1985. Mandatory child and spousal support enforcement and publicizing availability of child support enforcement services are also effective in FY 1986. Reports from the State Commissions on Child Support Enforcement are due by October 1, 1985. Last, but certainly not the least, the intercept of Federal income tax refunds for support arrearages of non-AFDC cases is authorized for refunds payable after December 31, 1985.

Questions Submitted by Senator Pete Domenici

CLOSING OFFICES

Question. There has been a plethora of news articles and leaked documents from the SSA that suggest that SSA has plans to close specific district offices (DO's) and data operations centers (DOC's). Does the Administration have plans to close any speciic DO's or DOC's?

Answer. The article and "leaks" you mentioned were inaccurate. We have no plan to close specific DOC's or DO's. At present there are branch offices scheduled for closing, for which decisions to close were made in FY 1984, prior to development of the long-range plan. However, the productivity improvement plan includes a project to strengthen existing service delivery reviews by implementing an ongoing, systematic and agencywide evaluation of our field office structure to ensure that we are providing

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service to the public in the most efficient and cost-effective manner.

Question. Are there existing criteria for closing these facilities? What are they? Do these criteria discriminate against small offices, like those found in New Mexico?

Answer. SSA does have criteria for closing district and branch offices which have been in effect since April 1980. Before closing any facility we consider the following factors:

- o the population of the service area,
- o the workload generated by the service area,
- o the distance to the closest SSA facility,
- o the availability of public and private transportation to the closest facility,
- o the impact on the level of service to the public due to the proposed closing,
- o the percentage of disadvantaged residents such as those with low income and low educational and literacy rates.

There are many factors involved in closing an office. Since the criteria do not specify that a facility be closed due to its size only, they do not discriminate against small offices, such as those found in New Mexico.

CONTRACTING OUT

Question. Are there plans for contracting out the functions performed by the Albuquerque DOC or the other DOC's?

Answer. There has been no determination made to contract out the functions of the Albuquerque Data Operations Center or any of the other DOC's. SSA has made a commitment to perform a management review of the data entry functions of the annual wage reporting process, most of which is performed in the three DOC's. The review is designed to improve the efficiency and effectiveness of both our procedures and workforce.

Question. If you contract out the DOC's, what effect would it have if the contractor's employees go on strike?

Answer. SSA has made no determination to contract out the DOC's but will review the data entry functions of the annual wage reporting process to improve the efficiency and effectiveness of the operating procedures and work force. The question you raise about possible strikes by private contractors' employees is not a unique problem for SSA--all Federal agencies which use private contractors, including the Department of Defense, face the same issue. However, there are some safeguards built into the process. First, all such contracts contain "no-strike" clauses. In the event that problems occur in spite of this, each contractor is required to provide a contingency plan, in the event of untoward circumstances, to ensure continuity of operations. Be

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assured that if we determine that it is advantageous to the Government to use contractor support, we will make every effort to ensure continuity of operations and to minimize any adverse effects that might result from union/management problems.

Question. What is the Administration position regarding the propriety and wisdom of contracting out such sensitive operations as posting of wage information, as is done in the Albuquerque DOC?

Answer. No decisions have been made to contract any of SSA's existing operations. SSA does have a commitment to perform a review of the data entry function connected with the annual wage reporting process; this function is presently performed, for the most part, in our three data operations centers.

The management review is being conducted as a first step in a process mandated by OMB Circular A-76. The process provides for the possibility of contracting work, but only following a lengthy, detailed study that shows whether the work can actually be performed more economically in the private sector. Systems security and Privacy Act implications are investigated during the management review phase of the A-76 process to insure that the work can be performed by a contractor and that it is not an inherent government function.

WORKFARE PROGRAMS

Question. Could the Social Security Administration provide a brief summary to the Committee of recent State experience in implementing and operating workfare programs for AFDC recipients?

Answer. Thirty-seven States have implemented at least one of the work program options made available in the last 4 years. Twenty-three of these States are operating Community Work Experience Programs--CWEP's. Many of these States, including New York, Oklahoma, West Virginia, Iowa, Georgia, and Pennsylvania, have reported that at least 20 to 30 percent of their CWEP participants are entering regular, unsubsidized employment. Surveys conducted in North Carolina and other States have shown very strong public support for this type of program, as well as improved public attitudes towards welfare recipients.

Recently we received results from two demonstration projects which show the effectiveness of CWEP and job search requirements in improving the employability of welfare recipients. Both projects used controlled experiments to measure the net impact of participation requirements--or the difference in employment rates for participants and nonparticipants. In a demonstration in Washington State, in two different sites, 30 and 39 percent of the participants in CWEP and job search activities found employment, compared to a 14 percent placement rate for nonparticipants. In San Diego, welfare mothers who participated in these programs experienced significant improvement in employment and earnings compared to those receiving WIN services. Employment increased 19 to 23 percent for these mandatory participants, while quarterly earnings increased 28 to 36 percent. Moreover, welfare expenditures for the regular AFDC caseload declined 7 percent and for the AFDC-UP caseload 14 percent.

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AFDC FISCAL LIABILITIES

Question. What is the current timetable for informing States of the status of their requests for waivers of FY 1981 fiscal sanctions in the AFDC program?

Answer. On April 25, 1985, the Secretary announced her decision on the FY 1981 AFDC waivers. Letters are being sent to States advising them of the basis for the decision. Official disallowance letters will follow advising States of the opportunity to appeal the disallowance.

Question. What percentage of the total sanctions does the Administration intend to collect?

Answer. As reflected in the budget for FY 1985, we estimate that $173 million could be collected in FY 1985 for AFDC fiscal disallowances, based on $74 million for FY 1981 and $99 million for FY 1982. The Administration's budget request for FY 1986 assumes collection of $414 million in AFDC fiscal disallowances for FY 1983 and FY 1984, based on $180 million and $234 million respectively.

Both the Michel Amendment and TEFRA make provisions for waiving a disallowance should a State fail to attain the target despite a "good faith effort." The amounts shown in the budget reflected an assumption that full collection would be made, without any waivers being granted. The Secretary recently announced her decisions on requests from the 28 States which sought waivers for the FY 1981 liabilities. Six of the 28 States received waivers of their liabilities with the result that in comparison with the $74 million that the budget estimated would be collected for FY 1981, we now estimate that we will collect $69.2 million, or approximately 94 percent of the total FY 1981 sanctions. As we consider State waiver requests, further adjustments to the budget may be needed if waivers are granted.

Question. Could SSA provide a summary of the amount of sanctions assumed to be collected in each of the past four budget requests and the total amount of sanctions actually collected?

Answer. The budget submitted by SSA for FY 1982 assumed the collection of $98 million in disallowances for excessive erroneous expenditures in the Aid to Families with Dependent Children (AFDC) program. The budget for FY 1983 assumed that $93 million in disallowances would be collected for FY 1982. The budget for FY 1984 showed total collections for AFDC disallowances of $210 million for fiscal years 1981 - 1983. These figures were revised in the FY 1985 budget to show the collection of $570 million in AFDC disallowances for fiscal years 1981 - 1984. To date there have been no collections of AFDC disallowances.

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Questions Submitted by Senator William Proxmire

WORK MEASUREMENT AND BUDGET ESTIMATES

Question. Commissioner McSteen, your prepared testimony places a heavy emphasis on productivity and the effective management of your Agency's workload. I'd like to discuss a related topic with you today--namely the feasibility of developing more refined work measures for staff budgeting by moving toward objectively established "should-take" standards. Last year in a response for the record you told the Committee that SSA's work measurement systems do record actual experience which represents the time it "does take" to process the Agency's workload but that this "does take" time is not built indiscriminately into your budget estimates. You also indicated that area directors examine procedures during periodic visits to field offices with a team from the regional office.

Why don't you use teams of professional work measurement specialists to do periodic studies which include an objective examination of operating procedures and the time it should take to carry out the procedures?

Answer: Special studies are conducted by task forces of work teams (including industrial engineers) on a "needs" basis. Recommendations for improvements in procedures are made based on their findings.

Conclusions about how long it should take to carry out procedures would be difficult to generalize, since local variations across the nation are an important determining factor. Such variations include employee experience levels (related to turnover and competing employment opportunities) and geographic/demographic influences on claims and postentitlement actions we handle. Although operating procedures can and have been standardized over time, these variations are inevitable.

SSA's work measurement system measures regional and national operating performance, including experience over time with unit times for various workloads. When new workloads are identified, we project anticipated national unit times for budget purposes, but regional staffing allocations take into account regional unit times which reflect the impact of local variations on processing times.

Question. Last year's answers for the record also included the statement that you modified processing time in your budget projections to take into account systems, policy and procedural, and other changes you expect in future years. This sounds dangerous to me. Suppose the expected changes don't materialize?

Answer. As you point out, any projected change may not occur as budgeted. In fact, in executing the budget there may be numerous deviations from the budget plan--actual workload receipts and processed, and actual production rates may be higher or lower than budgeted, salaries and other costs may be greater or less than in the budget plan, etc. For example, inquiries from the

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taxation of benefits are coming in lower than budgeted in FY 1985. Many times increases and decreases from the budget more or less offset one another. If they do not, SSA's Limitation on Administrative Expenses has a contingency reserve which is available explicitly for processing workloads not anticipated in the budget estimates and for other costs. We are requesting an increase in the contingency reserve from $50 million to $175 million in FY 1986 to provide flexibility to deal with the uncertainties associated with implementation of the disability reform legislation and the impact of automation on SSA's workforce.

Question. Rather than making adjustments in processing times based on changes you expect in future years, wouldn't it make more sense to use carefully engineered work measurement standards to develop "should take" time for these changes when they are in the process of being implemented?

Answer. Establishing engineered standards for field work could take several years to complete since there are many different field workloads, each with many subparts that require special attention and analysis. Because of the rapid changes occurring in processing times as a result of systems modernization, legislative and procedural changes, many developed standards would be outdated before they could be of much use. The effect of changes in staffing requirements from proposed changes in operations should be taken into account, whether using engineered standards or modifying actual unit times for expected change. It has been our experience that proposed changes can be estimated effectively starting with up-to-date actual experience and making adjustments for anticipated changes.

Question. Last year in a response for the record your Agency indicated it would find it difficult to use work standards because of geographical variations in your work force and in customers served. Have you ever conducted a work measurement study to determine how much difference such factors make?

How can you attribute the lack of work standards to geographical variations in the absence of a work measurement study to determine how much of an effect such variations in fact produce?

Answer. The current SSA work measurement system has demonstrated that there are regional differences due to a combination of factors, but there has been no study to determine quantitatively the value, or weight, of each factor that accounts for geographical differences. Even developing a logical methodology for such analysis, much less implementing it, would be costly and difficult.

Standards for how long it should take to carry out certain procedures would be difficult to develop for the nation as a whole since local variations are an important determining factor. For example, in some States, the processing of supplemental security income (SSI) claims varies in complexity depending on whether the States administer their own supplemental payments or request SSA to do so on their behalf. Other variations include employee experience levels and geographic/demographic influences on the

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claims and postentitlement actions we handle. Although operating procedures have been standardized and simplified over time, these variations are inevitable.

The influence of each of these factors varies among regions and local offices in terms of efficiency in processing workloads. Since SSA's primary responsibility is to provide timely and quality service to the public, the necessary allowances in the processing of workloads due to demographic differences must be taken into account in the management of a particular region or office. SSA's work measurement system measures regional and national performance, including unit times for various workloads. When new workloads are identified, we project anticipated national unit times for budget purposes, but regional staffing allocations take into account regional unit times which reflect the influence of local variations on how long work actions will take locally.

PRODUCTIVITY IMPROVEMENT

Question. Commissioner McSteen, can you tell us how you intend to accomplish the productivity improvement that is necessary to accomplish your proposed staff cuts? For example, do you plan to designate an individual who will be responsible for productivity improvement and will you establish specific annual and long range goals for productivity improvement?

Answer. I have announced the establishment of an Executive Steering Committee to develop and oversee the administration of the Full-Time Equivalent Multi-Year Management Plan. Mr. Nelson J. Sabatini, Acting Deputy Commissioner for Management and Assessment, has been designated overall lead responsibility for the project and will serve as Chairperson of the Committee.

Question. Last year, in a response for the record, the Committee was told that SSA productivity increased 6.6 percent in 1983 and was expected to increase 5.4 percent in 1984. Your workload in terms of initial retirement, disability, and supplemental security income claims did not change significantly over that period yet you used 88,163 staff years in 1982 and over 88,500 staff years in 1984. Why weren't you able to achieve staff reductions with a 12 percent increase in productivity over those 2 years?

Answer. SSA did achieve staff reductions during the period fiscal year 1982 through 1984. The record is as follows:

	FTE's	Workyears
FY 1982 Actual.....	83,622	87,977
FY 1984 Actual.....	81,532	87,825
Change.....	-2,090	-152

The data above apply to all accounts except for the Office of Refugee Resettlement. Workyears include overtime and nonceiling employment, as well as FTE's. The FTE and workyear numbers were adjusted for functional transfers to make them comparable.

Our estimate for productivity improvement in FY 1984 was not realized. The record is as follows:

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	Percent Change Over Prior Year		
	Volume of Work Produced	Number of Workyears Used	Productivity Increase (+) or Decrease (-)
1982 Actual....	+1.1	+2.5	-1.4
1983 Actual....	+8.3	+1.6	+6.6
1984 Actual....	-3.0	-2.4	-0.6

A major reason for the decline in productivity in FY 1984 was the moratorium on continuing disability reviews (CDR's). We had staff in place to work on CDR's, but the work was not there. We did not fire staff because the CDR process will start up again when the regulations to implement the Disability Benefits Reform Act of 1984 are in place, and we need trained staff to implement the law. The moratorium had not been anticipated in last year's budget estimates.

Question: One argument made last year against using work measurement standards was that the Systems Modernization Plan will result in a "series of improvements" in employee productivity but create such instability for some period into the future that you will not be able to evaluate and establish unit processing times that can be expected to last for any appreciable period of time. First let me say that I would hope and expect these times to change each year as you proceed to make your operations more efficient, but how do you judge the cost effectiveness of various systems modernization alternatives without using good work measurement standards as a tool?

Answer. Estimating the cost effectiveness of various systems alternatives is difficult whether work measurement standards or actual work measurement unit times are used as a take-off point. Standards are not essential to estimating cost effectiveness. Various work measurement techniques can be employed to measure cost effectiveness short of developing detailed "should be" standards. In addition to building on actual base unit times, work measurement studies are periodically conducted to determine the actual unit of times of subparts of the workload process (e.g., separating the claims interview process from data handling). Such breakdowns assist analysts in making estimates of the impact of various systems proposals on the subparts of the workload process.

HIGH PERFORMING OFFICES

Question. Last year, in a record response, SSA indicated it was studying 21 high-performing, highly productive district offices and planned to consider these offices' practices for wider application to improve performance in less productive offices. Have you in fact issued a report on your high producing offices that less productive offices can use or are you taking any other steps to apply the lessons learned to your other offices?

Answer. A final report on the results of the above-mentioned review was issued on December 6, 1984. A copy of the report was sent to every field office manager, Area Director and Regional Commissioner. The operations of 13 offices were studied to determine what allowed them to achieve high performance while making effective use of their human resources.

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The report identified 12 common characteristics of high performing offices. Among these were tight workload controls, innovative use of community resources, effective training, and adherence to basic management principles (communications, participatory management, etc.)

Each addressee of the report was urged to review the findings and determine the applicability of each to his or her situation. The body of the report included various specific approaches used by the high-performing offices for consideration by the addresses.

UNIT TIMES

Question. SSA's record response also mentioned an SSA analysis of variations in regional unit times which identified for each region those workloads with the greatest potential for productivity improvement. Have any unit times been reduced as a result of this study?

Answer. This review resulted in specific workloads targeted for improvement in several regions. During FY 1983, improvement was achieved in each of these regions. In FY 1984 we saw dramatic improvement in many of the identified workloads in these regions. Of particular note are reductions of unit times in the Boston Region - SSI redeterminations (41 percent reduction); and in the San Francisco Region - RSI claims (21 percent reduction) and SSI overpayments (36 percent reduction).

This effort was one part of a general review into all phases of productivity. Even regions with unit times better than national averages review their workflows and procedures with improved productivity as a goal. During the first 9 months of FY 1984, national unit times declined in seven of the nine largest workloads. These efforts are continuing into FY 1985.

INTERNAL CONTROL REVIEWS

Question. Commissioner McSteen, I understand that SSA reviewed internal controls at over 630 field offices during 1983 and 1984. However, internal control review activity at SSA headquarters during 1983 and 1984 was limited to six reviews covering property, plant and equipment; general ledger; sales; personnel administration; employee identification card file record system; and the general criminal investigation file record system. Apparently the review did not include your most important function--benefit payments. Why have you performed only six internal control reviews at headquarters and not reviewed your benefit payments system?

Answer. SSA performed only six internal control reviews at the headquarters level primarily because of the complexity of the operations involved and the necessity of integrating internal control reviews with ongoing management improvement initiatives.

Headquarters internal control areas are being addressed by the Systems Modernization Plan (SMP) and other management initiatives. There have been numerous internal and external audits, management reviews, and process reviews which are used as the basis for SMP requirements and corrective actions. For

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example, we have quality assurance systems in place to measure benefit payment accuracy and to help us identify the causes of overpayments and actions necessary to prevent them. All these efforts, however, have not been structured within an internal control framework, although they have included internal control considerations. In view of these many efforts, we are attempting to integrate and modify existing efforts before initiating new internal control reviews which may overlap.

We did review two benefit payment systems in 1984 - the Retirement, Survivors, and Disability Insurance Initial Claims and Postentitlement Systems. These reviews, however, were structured as accounting system reviews rather than internal control reviews, and we are presently attempting to restructure the reviews to serve as internal control reviews.

Questions Submitted by Senator Daniel K. Inouye

Question. The Child Support Enforcement program, now in existence for ten years, has not only successfully recovered child support payments but places the responsibility of child support back on parents. A major stumbling block for collection of support payments occurs when delinquent parents reside in another State. The Child Support Enforcement Amendments authorize $7 million for FY 1985 to improve interstate enforcement. What types of demonstration projects does this involve?

Answer. The $7 million authorized for FY 1985 to improve interstate enforcement involves the following types of projects:

1. **Those which encourage States to develop efficient and effective ways of handling interstate cases.**

2. **Those which augment and improve existing State efforts to pursue and respond to interstate efforts.**

3. **Those which develop, test, implement, and demonstrate new or innovative methods of interstate case processing.**

4. **Those which show a high promise of ready transferability to other States and of producing verifiable knowledge of demonstration results through definitive evaluation.**

Question. Are interstate recoveries of payments being made now?

Answer. States are cooperating with each other in the collection of child support. The Uniform Reciprocal Enforcement of Support Act (URESA) which was promulgated in 1950 and revised in 1968 (RURESA) to try to remedy the problems of spouses moving across State lines to avoid paying support, has been the predominant approach utilized by the States for cooperating in this effort. The original model act has been adopted by all the States, but in diverse forms. Under URESA, the initiating State files a petition in its court which then forwards the petition to the court in the responding jurisdiction. Officials in the responding State will conduct a hearing to determine if a support duty exists and, if so, establish an order for support in that State. The problem of enforcing the new order still remains.

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The availability of data for assessing interstate child support enforcement is insufficient, almost non-existent. Recordkeeping, generally at the State and local level has not been good, regardless of intra- or interstate data. We do know that interstate child support enforcement is taking place, but we are not able to adequately estimate or report the magnitude.

The Child Support Enforcement Amendments of 1984 rectify some of the problems with interstate enforcement. For instance, initiating and responding States both will be credited with the collection for computing incentive payments effective October 1, 1985. The mandatory wage withholding provision of the new law applies to interstate cases, as well as intrastate case. This provides that upon an obligor's noncompliance with an order, his or her wages or other income are to be withheld and applied to the child support obligation.

In addition, the Office of Child Support Enforcement has undertaken a major agency-wide initiative to improve interstate performance. Under the initiative, we have taken numerous actions to strengthen the enforcement of interstate cases. Some of these actions are a study of current interstate regulations, policies and procedures to determine if it is necessary to strengthen them and make them more uniform, publication of a URESA Law Digest, the Child Support Enforcement Handbook, and a Model Interstate Withholding Act (in conjunction with the American Bar Association), the development of effective ways of training staff involved in processing interstate cases, and the convening of an advisory panel to develop both a standardized URESA Referral Form and an Interstate Enforcement Transmittal Form.

Question. What is the rate of success for these collections?

Answer. Under the current reporting system, we do not have the necessary information to determine the success rate for interstate cases.

With the new reporting requirements of the Child Support Enforcement Amendments of 1984, the success rate for various activities of the program should be ascertainable. Effective October 1, 1985 (FY 1986), States will be required to report cases in which requests for assistance were received from other States, cases in which requests for assistance were sent to other States, and the corresponding number of cases in which collections were made. States will be required to report collections which were received from other States and will have the option, for purposes of calculating incentives, of reporting collections sent to other States. Under the new law, for purposes of computing incentives, support which is collected by one State on behalf of individuals residing in another State, will be treated as having been collected in full by each State. This should further encourage complete and accurate reporting of interstate activity.

Questions Submitted by Senator Lawton Chiles

A-76 REVIEWS

Question. Under the FY 1988-FY 1990 section of your memorandum, "Social Security--The Plan for Reduction in Employment" you mention in one sentence that you will determine the "efficacy" of contracting out various activities. In the next sentence you state that you will contract out. What is the

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purpose of studying the "efficacy" if your de facto position is that you will contract out by FY 1988-1990?

Answer. SSA plans to do OMB Circular A-76 reviews of various internal activities. However, SSA has no de facto position that we contract out this work.

We expect that the A-76 reviews will help management identify improvements to the way we do our work and probably enable us to do it at less cost than a contractor. In line with this, we project savings of 600 full-time equivalents in the outyears related to management improvements.

COSTS OF EMPLOYMENT REDUCTIONS

Question. Given the staff reductions that you contemplate, what will be the cost of severance pay, moving employees, moving expenses, office closings and openings, early retirement, and other administrative costs?

Answer. We do not yet know what the costs will be for retraining and relocating employees and for other changes associated with employment reductions and the impact of automation on SSA's workforce. One of the Agency's key objectives is to manage effectively the impact of automation on the workforce. Once we have a better fix on precisely which jobs and which locations will be most affected, we will be in a better position to estimate such costs. We plan no reductions-in-force.

Our FY 1986 budget request proposes language to permit use of the increased contingency reserve to deal with the impact of automation on the workforce. This language is intended to provide the flexibility needed to handle expenses such as retraining and relocation of employees.

Question. What are the costs for the need section (1-7) of your December 11, 1984 memo entitled "Condensed FTE Reduction Plan--Information?"

Answer. You are referring to the attachment to my December 11, 1984 memorandum to the Assistant Secretary for Management and Budget, which included a list of special needs for SSA to facilitate implementation of the long-range plan.

Although some of these "needs" do not have a cost (e.g., streamlined procurement authority), others do (e.g., training and relocation expenses). However, we do not yet have a good fix on what these costs will be. We are now working to identify which organizations, locations and employees will be most affected by systems modernization and future employment reductions. Once we have done so, we will be able to estimate costs for retraining or relocating those employees.

In SSA's FY 1986 budget request we have proposed language to permit use of the increased contingency reserve to deal with the impact of automation on the workforce. This language is intended to provide the flexibility needed to handle expenses like retraining and relocation of employees.

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I want to make another point about the list. This memorandum deals with a plan which was subsequently revised--to reduce the planned FTE reduction from 19,000 to 17,000 through FY 1990. As a result, number 6 in the list (to permit contracting out of annual wage reporting) is no longer needed.

EFFECTS OF EMPLOYMENT REDUCTIONS

Question. Have any studies been made on the impact of forced reassignments and relocations of employees, and staffing imbalances resulting from total attrition, while simultaneously implementing system modification on beneficiary services?

Answer. We continually study proposed work processing changes to identify the impact on the delivery of service. This study process begins with the initial proposal for a change and continues even after implementation. One such change we are studying is the Modernized Claim System. As the project develops we continually update our estimates and refine the system requirements to ensure that the quality of service will not suffer. We will conduct pilot studies of the new system in two field offices initially, expanding the pilot study to 18 additional field offices once we are satisfied with the initial results. We are studying all aspects of the system for the effects on workflow, staffing mix, processing times, product accuracy, and employee reaction, as well as the quality of public service. We will not implement the Modernized Claim System nationwide until we are certain that it will function properly. This policy applies to all other Systems Modernization Plan initiatives as well.

Question. Many of the staffing reductions are being attributed to systems modernization. However, much of the Systems enhancements are still being developed with many unresolved problems, especially in the software department. Are not staffing reductions which are offered as already justified really based on the untested assumption that the systems modernization will work?

Answer. Our budget request is for FY 1986, and we are confident that the budget request will enable us to provide quality service to the public. In addition, we have advised Congress of our long-range plans for employment reductions, just as earlier in 1982, we advised Congress of our 5-year Systems Modernization Plan. Our long-range plan is based upon certain assumptions, one of which is that SSA's investment in systems modernization will enable us to handle claims and other work with less manual processing.

We will provide information on our progress when we appear each year before this Committee.

Question. In section III--Impact of the Plan (December 11,1984 memo) with respect to data review technicians, development clerks and teletypists, and the district office final authorization function, you repeatedly raise the issues of employee morale, forced reassignment, massive retraining, high costs, labor relations problems and productivity. In light of

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these problems, how can anything but disruption of services occur?

Answer. As I have explained in an insert for the record, the document you are quoting from is not part of my December 11 memorandum to the Assistant Secretary for Management and Budget. Furthermore, we have identified management of the impact of automation on our employees and organization as a key Agency objective. We believe that automation and other management improvements will result in a better working environment.

STRIKES BY CONTRACTORS

Question. If you contract out the Data Operations Centers, what kind of effect will it have if the contractor's employees go out on strike or similar problems occur?

Answer. There has been no determination to contract out the Data Operations Centers (DOCs) or any of SSA's existing operations. SSA does have a commitment to perform an OMB Circular A-76 management review of the data entry functions of the annual wage reporting process, most of which is performed in the three DOCs. The review is designed to improve efficiency and effectiveness of both our procedures and workforce.

The question you raise about possible strikes by private contractors' employees is not a unique problem for SSA--all Federal agencies which use private contractors, including the Department of Defense, face the same issue. However, there are some safeguards built into the process. First, all such contracts contain "no-strike" clauses. In the event that problems occur in spite of this, each contractor is required to provide a contingency plan in the event of untoward circumstances, in order to ensure continuity of operations. Be assured that if we determine that it is advantageous to the Government to use contractor support, we will make every effort to ensure continuity of operations and to minimize any adverse effects that might result from union/management problems.

SSA PROCUREMENT PROCEDURES

Question. A primary factor in SSA's problems in the procurement of the SSADARS replacement (i.e., the Paradyne) terminals, was the speeding up of procurement timeframes and the reduction of management controls. Yet, in the Acting Commissioner's December 11, 1984, memorandum, it was stated that SSA needs "streamlined expedited procurement authority" to accomplish the desired staff reduction. Have procurement management controls been improved at SSA?

Answer. Yes they have. Within the Office of Management, Budget and Personnel (OMBP), we have taken action to elevate the contracts and grants management function within the organizational hierarchy to report directly to the Associate Commissioner, OMBP. We are also reviewing the staffing of that function to assure that adequate resources are available for them to carry out their responsibilities.

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Within the Office of Systems, technical support responsibilities associated with the acquisition process have been strengthened and realigned to create more effective checks and balances.

--A Systems Acquisition Management Staff (SAMS) has been established which reports directly to the Deputy Commissioner for Systems. It establishes technical acquisition policy and reviews for technical effectiveness and for coordinating acquisition strategy for all ITS procurements in excess of $100,000, including any proposed changes. Procurements up to $100,000 are the responsibility of the Systems Associate Commissioners, subject to sample review and monitoring by SAMS.

--The responsibility for the development of requirements, specifications, planning and direct support of the acquisition process (evaluating proposals, participating in negotiations, monitoring technical performance, accepting products and services) is placed under several Associate Commissioners, consistent with their functional responsibilities.

--Significant procurement actions (over $100,000) require recommendation by an Associate Commissioner, review by SAMS and approval by the Deputy Commissioner for Systems.

Question. What is the current SMP procurement approach (i.e., what Deputy Commissioner controls major SMP procurements and what Deputy Commissioner controls the procurement technical review group)?

Answer. The Deputy Commissioner for Management and Assessment has organizational responsibility for the Agency's procurement function and is responsible for the overall processing of all contracts within SSA.

The Deputy Commissioner for Systems has organizational responsibility for providing technical review and control. As stated above, this is accomplished through the SAMS which reports directly to the Deputy Commissioner.

Question. Is SSA still vulunerable to the same type of procurement problems that have occurred in the past?

Answer. SSA has taken positive actions to mitigate the types of problems encountered in the past. Most important is an increased management awareness of the necessity to safeguard the integrity of the procurement process.

In addition to the management controls and technical reviews discussed above, we have emphasized competitive procurements, which call for field-proven, off-the-shelf equipment that enjoys a broad base of customer acceptance and industry support. Through the appropriate use of industry-supported architecture/interface requirements, SSA has reinforced competition and provided a more realistic base for industry support.

Further, we now have a technical staff within Systems whose

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function will be to provide a systematic, independent testing capability. This involvement will continue throughout the life cycle of the acquisition.

REDUCTIONS IN STAFF POSITIONS

Question. In SSA's December 11, 1984, and February 22, 1985, memoranda a category referred to as "Reduce Staff Positions" reflected a potential FTE savings of 1,200. These positions were identified to GAO as staff performing administrative, policy formulation, public information and other similar tasks. Will this reduction affect any individuals involved in SSA security improvement efforts, in SSA's ability to promptly respond to legislative initiatives, or in the progress of the Systems Modernization Program (SMP). If so, how?

Answer. The specifics of how SSA's long-term reductions of staff positions will be applied to individual organizational components have yet to be worked out. Nevertheless, we can assure you that we will not take any action which might adversely affect the progress of the SMP or our security improvement efforts. The design of our new hardware and software systems has already improved our ability to make programming changes required to implement legislative initiatives more quickly with less manual intervention. Over the next several years, we will be redesigning a number of additional systems which will further enhance our ability to respond quickly to legislative mandates. These systems improvements include increased consideration of security requirements and safeguards, and thus should enable us to improve systems security with less manual review and oversight.

EMPLOYMENT REDUCTIONS DUE TO SYSTEMS IMPROVEMENTS

Question. How many of the planned reductions depend on timely completion of the tasks identified in the SMP? Which tasks?

Answer. We estimate that approximately 9,200 of the projected 17,006 FTE savings in SSA's 6-year plan will come from systems improvements. Most of the savings from systems improvements will come from claims modernization--savings of 3,325 FTE's are projected from FY 1987 through FY 1989 from modernization of the Social Security claims system, and savings of 2,000 FTE's are projected in FY 1989 and FY 1990 from modernization of the Supplemental Security Income claims system. Systems savings in the plan also come from:

- Specific improvements budgeted for FY 1985 and FY 1986 which have occurred or are expected to occur before the end of FY 1986, such as:

  --automation of the procedure used by field offices to furnish benefit payment information to State welfare agencies,

  --replacement of card readers with scanning devices for case control and folder location in the Office of Central Operations, and

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--improvements to the claims automated processing system to include cases formerly excluded from automated processing.

o A portion of the savings attributed to "ongoing" systems and procedural enhancements from FY 1987 through FY 1990. In our judgement, about 1,975 FTE's or about 60 percent of the 3,279 FTE savings for this factor may come from systems improvements.

Question. How do they relate to the staff reduction?

Answer. The savings from systems improvements are not directly related to the projected reduction in FTE's for staff/support functions. Staff/support functions are those which are not measured as a direct part of workload operations, but include computer programmers, policy specialists and employees who provide administrative/logistical services. These functions are concentrated at headquarters, but there are also staff/support personnel in the regional offices and program service centers. We plan to achieve staff/support savings from management improvements of these functions, which in some cases may include automation improvements. The specifics of how SSA's long-term employment reduction plan will affect each SSA staff/support organization have yet to be worked out. However, we can assure the Committee that staff/support reductions will not be taken in critical systems support areas which could adversely affect progress of the Systems Modernization Plan.

Question. How confident is SSA management that these tasks will be completed on time?

Answer. We are confident that the projected FTE savings through FY 1990 can be achieved. However we recognize that it is difficult to make precise estimates that far into the future. Some of the scheduled changes may not take place exactly as shown in the plan, and FTE savings from any one of the factors may be greater or less than the amounts estimated. Each year the plan will be reevaluated based on actual Agency workloads, achievement of automation goals and other factors, and will be adjusted accordingly. In her testimony before the House Appropriations Subcommittee, Secretary Heckler advised the Congress that she has:

"...secured an absolute guarantee that if there is any glitch in the introduction or phasing in of the new modernization equipment, there will not be a phasing out of personnel. The equipment must be in place and the system working before the personnel are phased out."

Question. What would be the impact of staff reductions if certain key elements of the plan (i.e., district office claims automation) fell behind by a year or more?

Answer. Each year when SSA prepares its detailed administrative budget for the upcoming fiscal year, the Agency will assess whether planned changes in staffing levels are appropriate given the state of Agency workloads, achievement of automation goals, and other factors.

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USE OF TEMPORARY EMPLOYEES AND SERVICE TO THE PUBLIC

Question: According to a union representative, a February 2, 1985 SSA document states that SSA could absorb FTE reductions by attrition and freezing of part-time positions and terminating temporary and probationary positions. The document, according to the union, goes on to state that "However taking such action would result in a serious deterioration in the level of service being provided." This statement contradicts your December 11, 1984, memorandum. How was this contradiction resolved?

If temporary help is hired for peak periods, how will the same level of service be maintained without these employees? I would like a copy of these documents for the record.

Answer. I have no recollection of a February 2, 1985 document. Our objective is to improve service and deliver it more efficiently. We are not contemplating any actions that would result in a deterioration in public service. SSA has used temporary help for peak periods on many occasions without deterioration of public service. For example, the entire annual wage reporting process is accomplished each year with seasonal employees.

A copy of the December 11, 1984 memorandum and the two pages of attachments follow. I wish to point out that this memorandum dealt with a planned reduction of about 19,000 FTE's through FY 1990. The plan was subsequently revised to show a reduction of about 17,000 FTE's through FY 1990. Since I have no recollection of a February 2, 1985 document, I am unable to provide it for the record.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

SMF

DEC 11 1984

Acting Commissioner of Social Security

Condensed FTE Reduction Plan--INFORMATION

Assistant Secretary
for Management and Budget

In accordance with our conversation at the meeting yesterday, attached is a condensed version of the plan for FTE reduction at SSA during the Fiscal Year 1986-1990 time period.

I am available to discuss this further if you desire.

/s/
Martha A. McSteen

Attachment

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Reductions in Social Security Administration Employment

THE PLAN

1. Reductions:

	FTE's
FY 1984 employment ceiling	81,552
FY 1985	79,207
FY 1986	77,625
FY 1987	74,725
FY 1988	70,800
FY 1989	65,600
FY 1990 (target)	62,600
Total Reduction (1985-1990)	-18,952

2. How Reductions to be Achieved:

	FTE's
--HHS '85/'86 Budget Request to OMB	- 4,355
--Proposed Amendment for Disability Benefits Reform Act	+ 428
--Modernize Social Security Claims Process	- 3,325
--Modernize SSI Claims Process	- 2,000
--Reduce Staff Positions	- 1,200
--Streamline Service Delivery	- 2,000
--Final Adjudication of All Claims in District Offices (Procedural Change)	- 1,000
--Other Systems and Procedural Changes	- 3,100
--Contracting Out (Annual Wage Reporting data entry, computer center operations, and programming for administrative/ management information function)	- 2,400
Total Reduction (1985-1990)	-18,952

3. Reporting

Commissioner will report quarterly to the Under Secretary on the progress in implementing the plan and the placement of affected employees.

THE ASSUMPTIONS

1. There will be no major new legislation, or Administration initiatives, to increase SSA's workloads.

2. There will be no reduction-in-force to achieve FTE reductions, except as required for functions contracted out.

3. For functions contracted out, specifications will provide opportunities for current employees to work for contractor in same location as present job.

4. Efforts will be made through a formal review process of the existing field offices to streamline service delivery. While this could result in eliminating 100 to 200 permanent facilities, we will strive to accomplish the objective without diminution of service to the public.

5. Plan (-19,000 FTE's) could not be carried out by original target of FY 1988 without significant reductions-in-force and disruption in service to the public. Time needed to accomplish systems changes, retraining and relocation of employees.

NEEDS

1. Early-out authority, under Civil Service Retirement, for the full life of the plan.

2. Provision for special transition resources for training, relocation of employees, severance pay and separation bonus incentive (may require legislation). These resources are for travel, transportation, contractual services and employee compensation.

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3. Legislation to permit employees whose jobs are contracted out to continue to participate and contribute to their Civil Service retirement (similar to legislation enacted for employees in PHS hospitals).

4. Sufficient dollar resources for agency operations, especially for systems modernization costs.

5. Streamlined, expedited procurement authority delegated to SSA, with appropriate procedural safeguards.

6. Reconsideration by IRS (or legislation, if needed) to permit contracting out of annual wage reporting.

7. Flexibility to SSA to manage achievement of FTE-reduction objective without OMB line-item controls and imposition of further restrictions (e.g., designated cutbacks by management function, etc.).

POSSIBLE IMPEDIMENTS

1. Delays in systems modernization efforts.

2. Adverse Congressional reaction (the plan could be misconstrued as an abrogation of President's commitment to exempt Social Security from budget reductions).

3. Delays due to protracted negotiations with American Federation of Government Employees on the process for implementing the plan as it affects employees of the bargaining unit.

4. Court-imposed standards for agency operations, processing times, etc.

ACQUISITION OF NEW COMPUTER TERMINALS

Question. SSA plans a major acquisition of at least 17,000 terminals for installation in its District Offices and Program Service Centers. (A draft specification for the terminals was issued in November 1984.) Following the issuance of this document, SSA identified a reduction of 17,000 FTE's during the next 6 years? How will the proposed reductions in staff affect the acquisition of these terminals? (i.e., does SSA still need 17,000 terminals?) C-16

Answer. Our current base requirement is for 22,500 terminals. These terminals will be used to support the modernized claims process. They will also be used to improve employee access to our master record systems and thus will enable us to provide timely responses to client inquiries.

Our base quantity allocation only provides terminals for functions now being automated. In addition, our base quantity allocation is limited to certain technical employees who will share these terminals. To prepare for the future, the contract provides for an option to buy additional terminals. As SSA continues to modernize its systems and place more systems data in an online environment, SSA will be moving away from a shared terminal environment toward a one-for-one ratio of technical employees to terminals.

The anticipated staff reductions do not change current terminal allocation planning because most of the reductions are related to decreased manual work, or other changes which either have been taken into account or are not related to terminal acquisitions in the field. To the extent that SSA finds a reduced

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need for future terminals as a result of staff cuts, we will simply not purchase additional terminals.

Question. Attachment III of the draft RFP provides an installation schedule that lists field office locations for terminal installation. If field offices are closed, how will the terminals scheduled for installation in the affected offices be used? How will the RFP and resulting contract cover a field office closing? Please provide any documentation that responds to these issues for inclusion in the report.

Answer. If field offices are closed, those terminals scheduled for installation in them would be relocated to other field offices in place of optional quantities planned for later installation, to enable each technical employee to have a terminal device available rather than sharing one. Even if some field offices are closed, the SSA workloads will be transferred to other field offices, and equipment will have to be relocated to support those workloads.

The contract will allow for SSA to change the installation location after giving a 60-day notice to the contractor. This will prevent SSA from being locked into a fixed installation schedule.

If an office is closed after the terminal equipment has been installed, the contract will contain provisions for the vendor to relocate the equipment to another SSA location.

LEGISLATIVE FLEXIBILITY OF COMPUTER SYSTEM

Question. What has SSA accomplished in the area of legislative flexibility? What are some specific achievements since 1982? What are some specific initiatives that are (a) under way; or (b) planned? If any initiatives are under way, what progress has been made with them? If improvement in legislative flexibility has been achieved, does SSA have quantifiable measures or concrete evidence?

Answer. Progress is being made in improving legislative flexibility; however, it should be understood that it will take another 3-4 years to make our ADP systems significantly more flexible. Significant improvement will be achieved only upon completion of the major aspects of the SMP--particularly the system design and development objectives of the Software Engineering Program.

Some of the SMP initiatives that have, and will, contribute to improved legislative flexibility include:

--The ADP Planning Process: As a result of SMP system management improvements, SSA now tightly controls the allocation of human resources within the Office of Systems through a formal ADP planning process. One of the important aspects of this process relates to improving our ability to react to legislative changes. For the past 2 years, the Office of Systems has dedicated a portion of our available staff to respond to both known and potential legislative mandates. Legislative projects are assigned a high priority

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in the planning process and employees are not assigned to other management initiatives until all legislative projects have been staffed for implementation.

In our current ADP Plan, we have allocated resources for 16 legislative projects in FY 1985 and 8 projects in FY 1986.

--Increased Hardware Capacity: Increased hardware capacity to support software development was acquired as a part of the SMP Capacity Upgrade Prgram. This has increased our test and development capacity and has enabled the Office of Systems to complete more software development work faster. Additional increases in test and development capacity are planned to further improve our ability to respond even faster to legislative changes (as well as to other initiatives).

In addition to test and development capacity, increased hardware capacity in our production environment has also improved the SSA ability to respond to legislative change. For example, the increased Central Processing Unit (CPU) and Direct Access Storage Device (DASD) upgrades acquired as a result of the SMP enabled SSA to respond quickly and effectively to the recent "Taxation of Social Security Benefits" legislation. Without that hardware, it would have been impossible to produce 40 million SSA-1099 forms without serious interruptions to normal daily operations.

--Software Improvement: Our ongoing software improvement initiatives call for realigning and restructuring the existing SSA software code. This improved flexibility will contribute to an improved capability to respond to legislative change. As a result of the SMP Software Improvement effort, all programmatic code has been realigned and planning is underway for the restructuring effort.

--Functional Requirements: One of the most significant initiatives that will improve the SSA capability to respond to legislative change is the development of detailed and comprehensive functional requirements for our automated systems. Such functional requirements will document the specific products, services and processing logic that is to be supplied by ADP systems in order to support SSA programmatic and administrative operations effectively. The availability of this documentation will make it much easier to communicate changes in ADP processing requirements resulting from legislative initiatives.

Functional requirements have already been defined for the title II claims process, the annual wage reporting operation and SSA debt management. Contracts will be awarded throughout the next several months for the development of functional requirements for the remaining programmatic processes.

--Redesigned Software: The new programmatic software that will be developed based upon the previously described functional requirements will be composed of comprehensive and cohesive software modules. The use of such functional modules will enable SSA to respond more quickly to legislative change.

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With this type of modern software in place, it will no longer be necessary to make changes to hundreds of computer programs in order to implement a single change to a basic SSA business function. Because each of the business functions will be performed by a single software entity, changes will be restricted to only the software component that performs the function that requires change.

This redesigned software will be developed and installed in the next 3-4 years. The new title II claims processing software is currently being developed and the first phase has been released into production on a pilot basis. The annual wage reporting and debt management software is also under development with both of these projects in the software design stage.

--Personnel Resources: The Office of Systems has placed considerable emphasis upon restaffing the technical positions required to maintain existing systems and follow through with our modernization plans. Technical staffing has been restored to the levels whi existed prior to the crisis period described in the SMP. This restoration of staff will contribute to the improved capability of SSA to respond to legislative change.

Question. Why does SSA's ADP plan not show a line item for managing and improving the adaptability and flexibility of the computer systems? What, if any, resources are regularly dedicated explicitly to managing and improving adaptability and flexibility?

Answer. Improving the adaptability and flexibility of existing data processing systems is not shown as a line item in SSA's ADP Plan due to the nature and complexities of the activities needed to accomplish this objective. There is no single category of improvement that will significantly enhance the SSA capability to quickly modify or redesign existing systems in response to legislative change. Improving systems flexibility requires some degree of change in all aspects of SSA systems management--software, hardware, personnel resources, as well as methods and procedures.

Enhancing the adaptability and flexibility of SSA systems is one of the primary objectives of the SSA Systems Modernization Plan (SMP). Each of the six programs that constitute the SMP contains specific objectives for upgrading the effectiveness and efficiency of systems. These modernization initiatives will all contribute to improving the flexibility of the SSA systems environment.

SOFTWARE DOCUMENTATION

Question. We understood that the SMP was going to extensively document existing software and systems and use that documentation to guide (1) responses to legislative changes; (2) replacement decisions.

Why has the SMP provided so little emphasis on this area? GAO has been informed that of SSA's 2291 software programs, SSA

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intends to retrospectively document 976 of these programs. Of the 976, we understand that 420 have been documented to date. Why has SSA decided to document less than 1/2 of its total programs? How many of the 420 programs which have been documented, were being documented before the SMP was announced in March 1982?

How can the impact of legislative changes be readily analyzed and quantified without good documentation of existing systems?

Answer. We are confident that we can deal with new legislative changes to SSA's programs with the approach that we have adopted to document existing software systems. We have proven this in implementing the Social Security Amendments of 1983, which required development of a new Payment History Update System in order to issue annual statements of benefits to all Social Security beneficiaries.

The original System Modernization Plan (SMP) called for a major "retrospective documentation" effort (to be conducted primarily via private contractors at a cost of $5 million over a 2-year period). While the scope of this documentation effort was not specifically defined in the SMP, it was generally understood that the retrospective documentation was to include all classes or categories of systems documentation and all "programmatic" systems.

When the SSA managers responsible for retrospective documentation examined this charter in relationship to the time and funds initially budgeted, they concluded that 2 years did not provide adequate time to complete the documentation effort, unless:

- o significantly more than $5 million for contractor support would be made available; or
- o a considerable commitment of inhouse (SSA) staff could also be made available to supplement the contractor effort; or
- o the scope of the effort could be significantly reduced.

These conclusions were based upon an appraisal of the amount of effort that would be required to produce the following classes of documentation which are generally accepted as the basic (minimal) categories needed to provide "complete" documentation of software systems:

- o Functional Requirements - defining what is to be done within and by the software system.
- o System Design Documentation - defining the structure and other physical characteristics of the system.
- o Data Base/File Record Specifications - defining the content and format of the data used and produced by each of the various software entities (programs) that make up the system.
- o Computer Program Specifications - defining the internal processing logic of each of the programs that make up the system.

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- o System Run Procedures - instructions for running the system in an operational environment.

- o System User Manual - procedures describing the methods to be employed by the users of the software system.

Based upon the evaluation of the scope of the retrospective documentation effort, the resources available and the many other important initiatives required for overall software modernization, we decided to modify the approach to software documentation. Various alternatives were considered to define an approach that would make the best use of available resources, and accomplish the basic objective of acquiring effective documentation of SSA software systems.

The approach that was adopted can be summarized as follows:

- o Functional Requirements - This class of documentation was considered to be the most important and the most costly to produce. The importance of functional requirements is based upon the strategic role that such requirements play in the development and maintenance of software systems. Because requirements define what should be done, they stand between the user and the system supplier--representing, in effect, a "contract" between the two groups defining what the system is to do. The useful life of functional requirements extends throughout the life of the system itself. Functional requirements are difficult to develop because they must be very specific; and yet, must be written so that they can be clearly understood--have the same meaning--to both users and systems developers.

  Before the SMP, written functional requirements did not exist for any of the SSA programmatic systems. Because of the scope of the SSA systems processes, it was the opinion of the SSA technical staff that it would take more than 2 years and $5 million to produce just this class of systems documentation. (This opinion was later substantiated by the projected costs for the development of "new" functional requirements needed to support the Logical Application Group (LAG) development effort.)

  SSA decided that the best use of time and money would be to develop functional requirements for the system that we want, rather than the system that we already have. Therefore, we have decided to develop comprehensive functional requirements only for our new systems represented by the LAGS--understanding that, because the basic SSA business processes will not significantly change, effective functional requirements will benefit both the "new development" and the "maintenance" environments.

- o System Design Documentation - Similarly, we decided to focus our efforts in the design documentation area on the development of detailed designs for our new software systems; and, to produce only general design documentation for our existing systems. The development of new design documentation is being accomplished via our LAG implementation efforts, following the standards defined by

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our Software Engineering Technology (SET) Manual. The development of general design documentation for our existing systems was assigned to our inhouse staff in the Office of Programmatic Systems (OPS) and is nearing completion.

- Program Specifications - Much like design documentation we are pursuing program documentation on two tracks. The LAG development efforts are producing very detailed program specifications for all new software being developed. Existing programs are being documented employing two basic techniques; i.e.,

  --General program specifications are being developed by OPS for all existing programs that perform basic SSA business (non-ADP) functions. This means that programs that perform only generic ADP functions (like sorts, merges, fan-outs, etc.) are not being documented.

  --The source programs themselves are being documented internally (by adding descriptive "comments" that explain the functions that are performed by specific modules or sub-routines).

  A total of 124 programs were documented prior to the initiation of the SMP. Of the 1,794 remaining programs to be documented, a total of 884 have been completed as of March 29, 1985. This inhouse documentation effort is scheduled for completion in December 1985.

  In addition to these current program documentation activities, we also intend to further refine our program documentation as a part of our Software Improvement initiative that we are currently planning with assistance from the GSA Federal Conversion Support Center.

- Data Base/File/Record Specifications - In this area, we decided to focus on the development of automated documentation methods using our Data Resource Management System (DRMS) and a "data dictionary" software package. Data base schemes, file and record definitions, and data element definitions are being loaded into our data dictionary. This will enable us to generate standardized, hardcopy specifications out of the DRMS (along with "copy statements" for program data divisions). While this effort will take 2-3 years to complete, it is well underway--focusing on the SSA programmatic "master" files.

- Run Procedures - In this area, we also decided to opt for an automated approach. While hardcopy run procedures existed prior to the SMP, many of these procedures were out-of-date and difficult to use. Rather than expend additional resources to rewrite these hardcopy procedures, we developed run "profiles" for our production jobs and loaded this information into a data base located in our National Computer Center (NCC). This data is used by a software package to automatically schedule jobs for execution. (The package also provides online access to these run procedures for operations personnel in the NCC.)

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- o User Manuals - SSA has complete user procedures for all of our existing systems documented within the Program Operations Manual System (POMS). We are also experimenting with providing users online access to POMS procedures as part of our Administrative/Management Information Engineering (AMIE) Program.

PROCESSING COST-OF-LIVING INCREASES

Question. GAO reported that 20,000 hours of computer processing were required to implement the 1981 benefit cost-of-living increase. This increase required changes to over 600 computer software programs. How many hours of processing were required, and how many computer software programs had to be modified to implement the 1985 cost-of-living increase?

Answer. The information reported by GAO was extracted from the testimony of Mr. Jack Svahn, former Commissioner of Social Security, on Friday, May 22, 1981 before the Subcommittee on Social Security and Subcommittee on Oversight on Automated Data Processing (ADP) Systems:

> "This makes even a seemingly simple operation like effectuating the scheduled cost-of-living increase a task of enormous complexity. The increase for this year required changes to nearly 600 computer programs, had taken 20,000 hours of programmer effort and will require 2,500 hours of computer processing time."

Mr. Svahn was referring to the 4-month period of SSA activity in preparation for the 1981 cost-of-living adjustment (COLA), not just 2,500 hours of computer processing time required to effectuate that initiative. The 20,000 hours referenced represented the total number of personnel work hours required to develop, test, validate and implement the software changes required to (1) convert monthly benefit amounts, within the SSA master files, and (2) modify ongoing operations to properly react to new benefit rates following the conversion cycle.

In 1984, it was necessary to modify only 80 software programs and 240 computer processing hours were required to accomplish a larger COLA workload. The 1984 COLA operations were completed in less than 2 days without adverse impact on the regular daily, weekly and monthly processing schedules. This achievement was the culmination of incremental improvements which were implemented for COLA operations in May 1982 and November 1983.

IMPROVEMENT TO LEGISLATIVE FLEXIBILITY

Question. Please explain how each of the components of the Systems Modernization Plan (Software, Capacity Upgrade, Data Base Integration, Data Communications, Systems Operation Management, and Administrative Management Information) have improved or will improve legislative flexibility?

Answer. Enhancing the adaptability and flexibility of SSA systems is one of the primary objectives of the SMP. Each of the six programs that constitute the SMP contains specific objectives

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for upgrading the effectiveness and efficiency of systems. These modernization initiatives will all contribute to improving the flexibility of the SSA systems environment.

- o The Capacity Upgrade Program (CUP) has brought SSA fewer but much faster central processing units (CPU's) and direct access storage devices (DASD) to conduct production workloads.

- o The Systems Operation Modernization Program (SOMP) has brought automated job scheduling and online tape management capabilities which significantly streamlined operations.

- o The Data Base Integration (DBI) program has brought DASD, the conversion of master and intermediate file from tape to DASD, the Data Management Subsystem (DMSS) and Master Data Access Method (MADAM) to manage both the data and the DASD.

- o The Software Engineering Program (SEP) has brought enhanced testing capabilities, tools and methodologies for job compressions and software replacement, and step refinement techniques which afforded incremental improvements.

- o The Data Communications Utility (DCU) program will provide SSA with a modern teleprocessing capability which will streamline SSA's operational environment and, thereby, improve the Agency's ability to absorb new legislative workloads.

- o The Administrative Management Information Engineering (AMIE) program will provide SSA with a modern management information capability and will improve the Agency's ability to better plan and manage the implementation of legislative initiatives.

ADP/TELECOMMUNICATIONS PROCUREMENT PRACTICES

Question. GAO recently reported that because of difficulties SSA encountered in procuring and installing data communication equipment from the Paradyne Corporation, local intelligence efforts may have been abandoned, an action which directly impacts SSA's ability to provide local intelligence and therefore had a negative effect on SSA's ability to respond to legislative changes.

What specific improvements has SSA made in its ADP/Telecommunications procurement practices to avoid a repetition of the serious problems identified by the General Accounting Office in its reports on SSA's ADP procurement management?

Answer. SSA has taken positive actions to mitigate recurrence of the type of problems encountered in the past. Most important, is an increased management awareness of the necessity to safeguard the integrity of the procurement process.

In addition to management controls and technical reviews, we have emphasized competitive procurements, which call for field-proven, off-the-shelf equipment that enjoys a broad base of customer acceptance and industry support. Through the appropriate

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use of industry-supported architecture/interface requirements, SSA has reinforced competition and provided a more realistic base for industry support.

Further, we now have a technical staff within the Office of Systems which will provide a systematic, independent testing capability. This involvement will continue throughout the life cycle of the acquisition.

Question. What role if any, will the Paradyne terminals play in SSA's planned communications network?

Answer. The existing Paradyne equipment does not have the features which will meet the long-range terminal requirements for SSA. Paradyne terminal configurations have already been declared obsolete and will be disposed of after they are fully depreciated and replaced; those that are on lease will be returned to Paradyne.

Question. Does SSA plan to purchase the Paradyne terminals still being leased?

Answer. We have no plans to purchase the terminals that are currently leased from Paradyne.

TRANSACTION PIN

Question. In the past GAO has encouraged SSA to implement a Personal Identification Number (PIN) in its telecommunications systems to identify all users of systems, and trace all transactions entered into the system. While the Agency continues to meet its daily, monthly and yearly schedules, ever-increasing problems are arising in the areas of data integrity, reliability and program fraud/abuse. Presently, none of SSA's automated systems include audit trails.

Could the SSADARS system accomodate a transaction PIN?

Answer. Yes. The SSADARS System has a PIN assigned to all users of the system. The PIN is basically a LOG ON identifier which is appended to each transaction entered into the system during that session. In order for the PIN to be carried all the way through any given process, all of the software that make up that process must be modified to:

--allow for the presence of the new data element (the PIN) on each of the input and output files within the process, and

--(optionally) react to the various values that might be recorded within the PIN field according to some set of functional requirements for that process; e.g., do not process any transaction that has a PIN with a value not included within a table of approved PINS for a particular type of action.

In the case of the Immediate Payment of Critical Cases (IMPACC) transaction, we made the necessary changes in SSADARS, Postentitlement and IMPACC to allow the PIN to be carried all the way through the process. This transaction PIN provides an audit

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trail for the IMPACC transaction which is the payment transaction most sensitive to fraud.

Question. Why hasn't SSA implemented the PIN on a transaction basis?

Answer. We have not made similar changes to other processes because it would require changes to several hundred programs--programs that we are currently trying to redesign and replace. It was decided, instead, to incorporate PIN's as we redevelop these systems. Incorporating the PIN within the existing software would be a significant undertaking--not because any of the software changes would be particularly difficult, but because so many record definitions would have to be changed, tested and validated prior to implementation.

Question. Will the Data Communications Utility (DCU) (SSADARS' replacement) provide a transaction PIN capability?

Answer. Yes; however, the data communications utility (DCU) is a telecommunications network only and will not be directly involved in the transaction PIN. Unlike SSADARS, the DCU will not contain transaction processing software. Security access control software will be resident on the mainframe computer housing each application, rather than as part of the data communications system as it is in SSADARS.

The DCU is a transparent conduit for data, or common network. As such, it will not require specific security controls. It will utilize dedicated circuits and will not have dial-up access.

Question. What security features currently not provided by SSADARS are planned for the DCU?

Answer. Improved physical perimeter security controls will be established at terminal sites as part of the office renovation activities to support the DCU and the modernized claims system.

Security of the data and application processes will be implemented at each processor site. A commercial security software product, TOP SECRET, will control the authority of individuals to sign-on to an application and to enter transactions. Authorities will be based on the user's specific job needs or function.

SYSTEMS SECURITY

Question. Risk Management is the systematic analysis of all ADP operational and support processes and activities in order to determine (1) the vulnerabilities of each process and activity (2) the likelihood of an event occurring that would exploit those vulnerabilities, and (3) what safeguards should be installed to protect the processes and activities. In its 1981 Systems Security Handbook, SSA recognized the need to perform "a large workload of risk analyses, simply because all operational processes have never been looked at in detail from a security standpoint."

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One of the areas in which SSA could be vulnerable to fraud, waste and abuse is in its telecommunications systems (SSADARS, BDTS). Has SSA completed a risk analysis in either of these two systems since 1981? If so, did the results require action on management's part to address identified weaknesses? If no risk analyses have been performed, why not?

Answer. We have not conducted a risk analysis of either the SSADARS or BDTS systems per se. We have, however, reviewed two of the major applications that function in those environments:

1. An internal control and audit study of the Retirement, Survivors and Disability Insurance processes was completed in September 1983. This study was conducted with the assistance of the Systems Engineering and Integration contractor (Deloitte, Haskins and Sells). Those recommendations which could be addressed within 6 months without software modification were scheduled for implementation. All other recommendations are being incorporated as the processes are redesigned within the Systems Modernization Plan (SMP).

2. An internal control and audit study of the Enumeration Process was completed in December 1984. Recommendations are being reviewed as part of the project to modernize the Enumeration Process.

SSADARS and BDTS are networks for communication with SSA application programs. The manipulation of information within the application programs represents a greater risk than the misuse of the network. We have chosen to concentrate our risk analysis activity on the processes rather than the networks as reflected above.

Question. In 1981 SSA employed a contractor to perform a risk assessment of its National Computer Center in Baltimore. What were the results of this study? When was it completed? What products were delivered? What was the total cost of the contract? Has this contract been terminated?

Answer. The major conclusion was that the physical security of the NCC was excellent. As stated in the final report "It is one of the best within the unclassified sites."

Specific highly detailed conclusions were listed as a series of recommendations. Most of the recommendations related to physical security and fire/safety conditions were implemented. Some of the recommendations either reflected a misunderstanding of the complexity of systems at SSA or encompassed recommendations that could only be implemented within the context of the SMP. Most of these have been addressed through organizational changes, and development of improved procedures under the SMP.

The contract was completed in June 1982, at a cost of $96,951. The only product produced by EDP Audit Controls was a report. This report has been used for guidance in the development and enhancement of security systems at the NCC.

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Question. According to HHS' ADP Systems Manual, a number of minimum security requirements and safeguards should be met. What action has SSA taken in the following areas of ADP security?

--Conducting background investigation on government and contractor personnel involved in the design, operation or maintenance of SSA ADP systems.

--Developing and maintaining contingency plans covering emergency ADP operations, backup operations and recovery plans.

--Ensuring inclusion of security safeguards in new or modified application system prior to implementation.

--Establishing internal procedures to ensure that all contracts include specified ADP security provisions.

Answer. We are taking the following actions:

1. We are presently implementing a personnel security program which identifies ADP sensitive positions and requires background investigations (BI) or National Agency Checks on persons hired for those positions. Implementation is taking place in two phases. On October 18, 1984 the Acting Deputy Commissioner for Management and Assessment initiated Phase I of the program which identifies existing ADP sensitive positions and certifies incumbents of those positions. SSA servicing personnel offices have already accomplished much of the work required in this phase.

   The second phase of the effort will begin on May 15, 1985. A procedure will be implemented supporting an ongoing process for establishing and filling ADP sensitive positions. This process includes guidelines defining when a BI is needed, procedures for initiating a BI, a National Agency Check and credit check requirements and personnel office contact points.

   Contractor staff do not operate SSA systems. We are presently developing security policies related to ADP contractor staff and will soon define a program in that area which fulfills regulatory requirements.

2. A guide for developing contingency plans for emergency/ADP operations at SSA field locations has been developed. During FY 1985, we will ensure that all facilities have adequate contingency plans.

   We are implementing a broad based backup recovery plan for offsite operations critical to the National Computer Center. This plan addresses backup operations for software and data files and the acquisition of an offsite facility, which is in the procurement stage.

   In addition, a Distributed Data Processing (DDP) task force has been established in order to develop a DDP

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design process covering emergency ADP operations, backup operations and recovery plans.

3. We have several processes which support ADP systems security throughout the entire system development life cycle. SSA requires that functional requirements for proposed systems and changes to an existing system contain a statement of security needs. This statement is compared by our security staff with a prescribed set of objectives to insure that the necessary consideration is given to security. The change control operation requires that a security officer sign off for specific types of changes such as new file creation or an increase in the number of persons gaining access to a file. Additionally, all system changes require line management authorization indicating that security requirements were met. We are developing internal audit support capability using an automated control and audit test facility. We are implementing TOP SECRET, an automated software package which gives management control of access to valuable system resources. We have established a security officer structure including requirements, development and operations staffs; we have separated production and test facilities and software libraries. Design and peer reviews are conducted which consider security aspects of systems; and automated comparisons are made of current versions with previous versions to identify changed code.

4. We are integrating security-related requirements into our procurement and contracting procedures to be sure that security aspects are adequately covered. The following are the primary features of the procedure:

   --Procurement documents (e.g., Requests for Proposals) will contain reference to SSA and HHS security policy documents available to the bidders, and will specify any security requirements unique to the RFP.

   --In all contracts that involve contractor personnel to be onsite as part of the contract, language will be included that binds contractor employees to SSA requirements regarding background investigations. Generally, the requirements for contractor personnel are the same as for SSA employees.

   --Procedures have been established in SSA to ensure that proper clearances have been obtained prior to contractor personnel reporting onsite.

OFFICE OF SYSTEMS SECURITY POLICY

Question. Previous reports on security have repeatedly pointed out the severe fragmentation of security activity and responsibilities at SSA. We understand that the Office of Systems Security Policy was created nearly a year ago to provide planning, implementation and evaluation of a comprehensive systems security program for SSA's Office of Systems components. While the goal of

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this office is to centralize security efforts within the Office of Systems, nearly a year after its creation the Office still has no official role.

What is the mission of this office, and how is this mission expected to be accomplished? How many staff are planned for this office? What is its role in SMP activities? What role will this office play in field office security?

Answer. In the spring of 1984, the former Deputy Commissioner for Systems transferred the Systems Security Staff from the Office of Systems Integration to the the Office of Strategic Planning and Integration (OSPI), a new component reporting directly to the Deputy Commissioner. The OSPI has now been restructured and renamed the Office of Planning, Support and Integration (OPSI). A new mission statement for OPSI has been completed which includes the Systems Security and Integrity Staff. Ten employees are being assigned to this staff and one remaining vacany will be filled. In addition, each Associate Commissioner has designated a Systems Security Officer to represent his or her respective component. Formal approval by the Department of Health and Human Services is expected.

The primary mission of this staff will be the development and coordination of systems security policy within the Office of Systems in accordance with policies at higher levels (i.e., agency, departmental, government-wide policies). Some specific functions which this office will perform include developing a systems security program, defining and coordinating Office of Systems input to the SSA Automated Information Systems Security Plan required annually by HHS, identifying data system sensitivity/criticality identification, defining an Internal Control Review process, identifying and fulfilling system security training needs, monitoring Office of Systems efforts in the personnel security area, and integrating security aspects with other system development life cycle activities.

The Systems Security and Integration Staff's role will be to serve as the focal point for indentifying security needs and developing appropriate policies to implement security improvements.

This staff's role in SMP activities will be the same as that for non-SMP activities; no distinction is being made between activities because the policies developed by this staff will apply to all SSA Office of Systems components. There are, however, some specific SMP activities which emphasize systems security. For example, as part of the Capacity Upgrade Program (CUP), a major project underway in the Office of Systems is the implementation of a resource access control system which will limit unauthorized use of system resources. The Claims Modernization Program (CMP) includes several systems security features. Component security officers have also been designated specifically for the CMP and the software engineering program.

This staff will have no direct role in field office security which is the responsibility of the regional offices in cooperation with the SSA Systems Security Officer (SSASSO) who is in the Office of Assessment. Of course, policies established within the

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Office of Systems may affect the users (i.e., the field offices) and these policies will then be coordinated with the SSASSO. In the regions, the regional security offices (RSO's) are the counterpart to the central office component security officers (CSO's). They ensure the implementation of mandated safeguards and provide service to the SSASSO who is the focal point for the SSA security program.

Questions Submitted by Senator Tom Harkin

ORR GRANTS MANAGEMENT

Question. I understand that both the General Accounting Office and the Inspector General's Office at HHS investigated the grants management and administration functions at the Office of Refugee Resettlement. Please provide an update on how your grants management procedures, policies and personnel have changed to respond to the findings of these two organizations with respect to the administration of the refugee programs.

Answer. Upon completing their review, the General Accounting Office (GAO) and Department of Health and Human Services, Office of the Inspector General's auditors briefed me on their studies of practices which the Office of Refugee Resettlement (ORR) had followed in the award and administration of grants. In response, I presented the auditors with a self-assessment which included improvements I planned to institute to strengthen overall grants management in ORR. In their draft report the GAO concluded that the "planned actions, if effectively implemented, should improve ORR's grants management process".

To help monitor ORR's progress in making the improvements outlined, the GAO recommended and the Commissioner of Social Security required that ORR submit periodic progress reports. As these reports have illustrated, ORR has made and sustained significant gains in all areas of concern.

For the purposes of reporting, the concerns fall into four areas: the extent to which grantees are complying with reporting requirements; the extent to which program monitoring is being carried out; the extent to which noncompetitive awards are made and the adequacy of existing resources to maintain an effective grants administration program.

Grantee Compliance with Reporting Requirements

Foremost among the GAO's concerns about grants management in ORR was the concern that ORR inadequately monitored its grants. Since responding to the draft GAO Report, ORR has made steady progress in this area. For example, the GAO reviewers found that of the reports due in the audit sample of grants funded in FY 1980 and FY 1981, 75 (or 22 percent) of the 340 financial status reports and 106 (or 44 percent) of the 240 performance reports were missing.

In our initial six-month report, we already noted significant improvement. For that reporting period, only 6 (or 8 percent) of the 71 financial status reports and 14 (or 21 percent) of the 66

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performance reports due had not been received by ORR. For the subsequent reporting period, we were pleased to note further progress. As of April 30, 1984, only 6 (or 7 percent) of the 81 financial status reports and 5 (or 10 percent) of the 63 performance reports due had not yet been received by ORR. For the current reporting period none of the 182 financial status reports and only three (or 2 percent) of the 143 performance reports due are outstanding.

Although no grants were suspended or terminated in the current reporting period as a result of a grantee's failure to submit required reports, release of funds under several new or supplemental awards was restricted pending submission of reports overdue under the previous year grants.

As planned, ORR has made a practice of advising grantees of upcoming report due dates and in each instance of a grantee's failure to submit a required report, directing submission of the report or an explanation of the failure to submit.

Program Monitoring

In its initial six-month report, ORR noted excellent progress in virtually all areas involving grant reporting, but acknowledged the need to further strengthen its documentation of grantee-submitted report review. Although ORR does use other monitoring methods as well, staff review of grantees' fiscal and program progress reports is its principal means of assessing grantee performance.

According to the GAO, at the time of the audit there was little evidence that grantee monitoring reports, when received, were reviewed. Our initial report showed good progress but the need for additional improvement. At that time, 56 (or 86 percent) of the 65 financial status reports and 19 (or 37 percent) of the 52 program progress reports received for the period had been reviewed. For the reporting period ending April 30, 1984, 75 (or 100 percent) of the 75 financial status reports and 32 (or 56) percent of the 57 performance reports received had been reviewed.

For the current reporting period, 182 (or 100 percent) of the 182 financial status reports and 137 (or 98 percent) of the 140 performance reports received had been reviewed. Documentation of progress report review is now virtually as complete and reliable as documentation of financial status report review.

Competition in ORR's "Discretionary" Programs

In addition to questions concerning grants administration, the GAO addressed ORR grantee selection and award procedures. While acknowledging that circumstances limited the potential for competition in some ORR categorical programs, the auditors felt that ORR should more fully explore opportunities for competition where they existed.

In FY 1984, ORR made a total of 44 new and supplemental categorical grant awards. Individual awards were issued under one of eight announced programs or as special projects. As to award method, grants were issued on the basis of competitive review, through an announced formula allocation process, in response to an urgent need,

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or in isolation as unsolicited or special case submissions. Since the Department's standard for the selection of grantees is competitive, awards issued through noncompetitive means were documented and justified as exceptions.

Adequacy of Resources

The maintenance of an effective grants administration program is dependent, largely, on the adequacy of staff and other resources. In its self-assessment, ORR identified the need for additional formally trained grants management personnel. At the time ORR submitted its first semi-annual report, the Office was reviewing applications for a grants management specialist vacancy. When we submitted the last report, that position had been filled and ORR had created and filled a new grants officer slot. At present, ORR's grants office is fully staffed and adequately supported.

CONSULTING SERVICES

Question. On page 34 of your budget justification, you indicate that $100,000 is needed for contractual services. Please provide more detail on exactly what these funds will be used for and explain particularly why these services cannot be performed in-house.

Answer. The funds requested are for consulting and related activities in support of the refugee resettlement program. Specifically, funds are used to convene experts from outside the Federal government (such as State and local officials and public and private voluntary agencies) to provide special technical knowledge and expertise in grants panel review (for instance, for funding and awards for demonstration projects authorized by the Wilson/Fish Amendment and ORR's national discretionary social services programs) and other key aspects of the domestic refugee resettlement programs, providing local and unique perspectives that do not exist on the national Federal level.

Question. What prompted the need for the special technical assistance study? What deliverables will be provided and on what schedule? How will the results of this study be used by the Office of Refugee Resettlement?

Answer. The technical assistance referred to is not one specific project or study, but, rather, it is a category of short-term special technical assistance provided by outside experts to ORR on unique issues concerning (international and domestic) refugee resettlement. Examples of this type of technical assistance would be the planning and implementation of demonstration projects under the Wilson/Fish Amendment and planning for the implementation and monitoring of the Lungren Amendment provision (to make voluntary agencies legally and financially responsible for the basic needs of refugees during their first 90 days in this country in FY 1986).

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HEALTH CARE FINANCING ADMINISTRATION

STATEMENT OF CAROLYNE K. DAVIS, ADMINISTRATOR

ACCOMPANIED BY:

JAMES L. SCOTT, ACTING DEPUTY ADMINISTRATOR
JOHN D. MAHONEY, DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT AND ADMINISTRATIVE SYSTEMS
DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator WEICKER. Our final witness this morning is Dr. Carolyne Davis, Administrator of the Health Care Financing Administration. Dr. Davis, why don't you introduce your colleagues and then proceed with your statement. Your entire statement will be inserted in the record at this point in its entirety.

[The statement follows:]

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STATEMENT OF CAROLYNE K. DAVIS

I am pleased to be with you today to present our FY 1986 budget request for the Health Care Financing Administration (HCFA). This budget plays a crucial role in serving the 51 million elderly, disabled and poor who depend on Medicare and Medicaid to help meet their health care needs. At the same time, the need to discipline spending while assuring continued access to health care by the elderly and disabled remains a delicate and pressing issue for the nation.

Before I highlight the specific appropriation items of interest to this Subcommittee, I want to outline our philosophy and overall approach in developing these budget request proposals. When this Administration took office, Medicare costs were rising at 18.7 percent a year. In FY 1986 that increase is projected to decline to 4.6 percent. This has been accomplished through reforms that have maintained access to quality care by a growing number of beneficiaries. The Prospective Payment System (PPS) for hospital reimbursement (paying all acute-care hospitals a fixed amount according to diagnosis) appears to be a major factor in slowing the rate of increase for the Medicare program.

Overview

While maintaining the quality of health care, our 1986 budget reflects the Administration's continued commitment to holding the line on health care costs, doing our part to reduce the deficit, and maintaining the Medicare trust funds' solvency. This budget may be viewed as an integral part of a government-wide policy to limit Federal outlays while continuing to carry out the mission of our programs. In order to insure continued moderation of cost increases, this budget proposes a number of legislative and regulatory initiatives aimed at reducing the growth rate of expenditures. Even with these proposals, overall spending for Medicare and Medicaid will increase by $2.2 billion from FY 1985 to FY 1986.

Savings Initiatives

In Medicare, we plan to achieve spending control by maintaining current hospital prospective payment rates and reimbursement rates to most other providers at FY 1985 levels while continuing to encourage competition in the health care sector. In Medicaid, we would provide States with incentives to structure their programs in the most cost-effective manner by providing limits on both program and administrative costs combined with increased flexibility to manage their programs. Together, our proposals will reduce Federal health care expenditures by $5 billion in 1986 and by $49 billion over the next five years.

I would now like to proceed with a brief overview of our appropriations request.

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Grants to State for Medicaid

The Medicaid program provides grant funding to all States and the territories for medical care for approximately 23 million low income persons. Our FY 1986 request of $23.7 billion reflects the following legislative proposals:

1) To limit FY 1986 Federal expenditures for medical assistance payments (other than Puerto Rico and the territories) to $22.2 billion and to constrain future years' growth to the medical care component in the consumer price index; and

2) To limit Federal expenditures for FY 1986 Medicaid administration costs, including funding for State certification and fraud control units, to FY 1985 levels.

Although it has been significantly reduced over the last several years, medical care price inflation continues to increase at a rate in excess of the general economy. Price inflation alone accounts for nearly two-thirds of the States' projected Medicaid increases for FY 1986. Our budget request seeks to stem the rate of program growth by inducing States to adopt further cost containment efforts which we believe they can make. For example, we estimate that the current Medicaid eligibility error rate of 2.7 percent represents erroneous Federal expenditures of $400 million, and the General Accounting Office reports that Medicaid still covers approximately $500 million annually in uncollected third-party payments. To facilitate implementation of efforts to achieve additional cost effectiveness, the Administration will propose a number of measures to give States additional program flexibility. In addition, a hardship pool of $300 million will be available in FY 1986 to provide relief to those States which, despite aggressive cost containment efforts, experience uncontrollable increases beyond their funding limit.

Payments to Health Care Trust Funds

The payments account contains monies appropriated to the Medicare trust funds. Federal matching funds supporting the Supplementary Medical Insurance program make up the bulk of this account. In addition, the account includes funds to support benefits under the Hospital Insurance program for those beneficiaries grandfathered into entitlement, and military service credit payments enacted by the Social Security Amendments of 1983.

Our FY 1986 request for this account is $19.7 billion - an increase of less than $1 billion or 4.8 percent. It is composed of the following elements:

- Federal payment for Supplementary Medical Insurance (SMI) -$19.0 billion;

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- Hospital Insurance for the Uninsured - $554.0 million;
- Military Service Credits - $91.0 million; and
- Hospital Insurance for Uninsured Federal Annuitants - $12.0 million.

One of our legislative proposals would gradually increase the proportion of estimated expenses covered by the SMI premium revenues to 35 percent by 1990. This proposal, if enacted, could reduce our appropriation request by $736 million for FY 1986, while representing only a small increase per beneficiary.

Program Management

This account provides funding for management activities related to Medicare and Medicaid. The total FY 1986 request of $1.2 billion is broken down into $82.4 million appropriated from general funds, and $1.1 billion authorized to be transferred from the Medicare trust funds. Overall, we have worked to reduce ongoing operating costs and to shift resources to enhance the recovery of trust fund dollars and to develop new information as a basis for future reforms of the system.

The FY 1985 budget for Program Management includes a recission of $5.8 million as provided by Section 2901 of the Deficit Reduction Act of 1984. Of this account, $1.4 million has been taken from the Research, Demonstrations and Evaluation budget, $100,000 from the State Certification budget, and $4.3 million from the Administration Costs budget.

The Program Management request for FY 1986 covers the following program activities:

1. **Research**

Results gained from research, demonstrations and evaluations produce knowledge about ways to more effectively manage the Medicare and Medicaid programs. Previous investments in this area have produced information critical to the development of legislation and program changes such as the prospective payment system, and expansion of HMOs. We are requesting $22 million for research in FY 1986. This budget reflects the Administration's commitment to improve targeting of limited Federal research resources and reflects:

- Phaseout of the efforts that have been completed (for example, selected long-term care and hospice demonstrations);
- Continuation of high priority projects, including Congressionally mandated studies, that require Federal funding in FY 1986 ; and

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- Selected new projects which are consistent with the Administration's priorities and would provide essential information for further reform of reimbursement systems and improve efficiency in service delivery.

2. **Medicare Contractors**

This budget activity provides funding for operating costs incurred by our fiscal agents, primarily insurance companies, in administering the Medicare program. Key functions for which Medicare contractors are responsible are claims processing, payment safeguards and service to Medicare beneficiaries. We are requesting $935 million for this budget activity in FY 1986. This amount represents approximately 1 percent of Medicare benefits paid by contractors. We are also submitting two legislative proposals which would improve contractor operations and would save $5 million in FY 1986. The first would allow us to process Part A claims on a flow basis; and the second, to eliminate the separate carrier for Railroad Retirement Board claims.

The FY 1986 budget reflects a continued emphasis on strengthening payment safeguards, including audit and medical review activities. The successful implementation of the new Prospective Payment System has made these critical activities even more cost beneficial. The budget also reflects the strengthening of Medicare secondary payer efforts by contractors to ensure appropriate payment by third parties where they are primary payer. Funding increases to strengthen these efforts are offset by continuing decreases in claims processing costs.

3. **State Certification (Medicare)**

The State Certification program is responsible for ensuring that both institutional and non-institutional providers and suppliers rendering health care services to Medicare patients meet acceptable quality and safety standards. Annual agreements are negotiated with State agencies to perform surveys of health care facilities in accordance with explicit criteria.

The FY 1986 request for Medicare certification activities and program support services is $49.8 million. This is in addition to the resources required for Medicaid survey and certification which are included in the Grants to States for Medicaid appropriation request. Our FY 1986 request remains at approximately the same level as in FY 1985 and provides for overall survey coverage of approximately 65 percent of the providers and suppliers participating in Medicare. Within that total level of funding, we will continue to survey 100 percent of long term care facilities and hospices.

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4. **ESRD Network Coordinating Councils**

End-Stage Renal Disease (ESRD) Network Coordinating Councils are responsible for reviewing quality of care and efficient utilization of resources devoted to kidney dialysis and transplantation services. However, we believe that the role the Councils perform can be adequately assumed by other organizations that perform these functions for all Medicare services. Therefore, no funds are requested in FY 1986 for ESRD Network Coordinating Councils. We will be making administrative changes which will allow the Councils' quality of care and data collection activities to be carried out by other organizations funded by HCFA, such as PROs and contractors, while some activities will be assumed by HCFA staff. This change will allow comprehensive quality and utilization review of the full range of Medicare services provided to ESRD beneficiaries.

5. **Administrative Costs**

Administrative costs include HCFA staff and operating expenses required to manage the Medicare and Medicaid programs. Major functions are the articulation of policy, regulations, and guidelines regarding program coverage, beneficiary eligibility, reimbursement and conditions of participation; the negotiation of agreements with fiscal agents and grantees; and the monitoring and evaluation of contractor, grantee, and health care provider performance.

We are requesting $204.6 million for FY 1986. This represents a decrease of $12.3 million from the FY 1985 estimate. Most of this decrease results from a staff reduction of 180 FTE's and the 5 percent Government-wide pay cut that is being proposed.

The Committee should be assured that HCFA intends to achieve the required FTE level through attrition and not by adverse actions. Within the reduced level of staffing resources, HCFA will continue the efforts, begun in FY 1985, to intensify its "look behind" of Intermediate Care Facilities for the Mentally Retarded (ICFs/MR). These efforts assure the delivery of quality health care under Medicaid by validating State agency decisions made to approve participation for only those providers which meet Federal standards.

Our request for FY 1986 maintains approximately the same level of support as in FY 1985 to modernize the ADP systems of the Agency. The focus of the ADP PRISM program will change, however, from that of planning and design to actual systems development.

This concludes my remarks, Mr. Chairman. I will be happy to answer any questions the Subcommittee may have.

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INTRODUCTION OF ASSOCIATES

Dr. DAVIS. Thank you very much, Mr. Chairman. On my far left is Mr. Dennis Williams, Acting Deputy Assistant Secretary of Budget from our departmental Office of Management and Budget, on my direct left is Mr. John Mahoney who is Director of the Office of Financial Management and Administrative Systems for the Health Care Financing Administration; and to my right is Mr. James Scott who is the Acting Deputy Administrator of HCFA.

BUDGET HIGHLIGHTS

Dr. DAVIS. Let me just briefly highlight our presentation today, Mr. Chairman. Our 1986 budget reflects our continued commitment to hold the line on health care costs, to reduce the deficit and to maintain the solvency of the Medicare trust funds.

In order to ensure the continued moderation of cost increases, this budget proposes a number of legislative and regulatory initiatives aimed at reducing the growth rate of expenditures. Even with these proposals, the overall spending for Medicare and Medicaid will increase $2.2 billion from fiscal year 1985 to 1986.

In Medicare, we plan to achieve spending controls by maintaining the current hospital prospective payment rates and reimbursement to most other providers at the fiscal 1985 level while continuing to encourage competition in the health care sector.

In Medicaid, we would provide States with the incentives to structure their programs in the most cost-effective manner by providing limits on both program and administrative costs combined with increased flexibility to manage their programs.

Together, these proposals will reduce Federal health care expenditures by $5 billion in 1986 and $49 billion over the next 5 years.

MEDICAID

The fiscal year 1986 request for grants to States for Medicaid is $23.7 billion. This reflects the legislative proposals that I mentioned.

PAYMENTS TO HEALTH CARE TRUST FUNDS

The fiscal year 1986 request for payments to the health care trust funds is $19.7 billion. This represents an increase of less than $1 billion, or 4.8 percent.

If our legislative proposals are enacted, our appropriations request would be reduced by $736 million for fiscal year 1986.

PROGRAM MANAGEMENT

The fiscal year 1985 program management budget includes a rescission of $5.8 million as provided for by section 2901 of the Deficit Reduction Act of 1984.

The fiscal year 1986 program management request is $1.2 billion, which covers the following kind of activities:

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RESEARCH

We are requesting $22 million for research in fiscal year 1986. This is a reduction of about one-third over the fiscal year 1985 level. It represents our intent to target our limited Federal resources.

MEDICARE CONTRACTORS

The fiscal year 1986 request for the Medicare contractors is $935 million. This request reflects a continued emphasis on strengthening our payment safeguards which include audit, medical review, and Medicare secondary payer activities.

MEDICARE SURVEY AND CERTIFICATION

The fiscal year 1986 request for Medicare survey and certification activities is $49.8 million. This request is approximately even with the fiscal year 1985 level.

ESRD NETWORK COORDINATING COUNCILS

The end-stage renal disease [ESRD] network coordinating councils are responsible for reviewing quality of care and efficient utilization of resources. We believe the role of the councils can be assumed by other organizations now performing similar functions for all other Medicare services. Therefore, no funds are requested in fiscal year 1986 for the councils.

ADMINISTRATIVE COSTS

The fiscal year 1986 request for administrative costs is $204.6 million, which reflects staff and operating expenses required to manage Medicare and Medicaid. This request represents a $12.3 million decrease from the fiscal year 1985 level. Most of the decrease results from a staffing reduction of 180 FTE's and the 5-percent Governmentwide paycut that is being proposed. I should point out that we intend to achieve the required FTE level through attrition, not through other adverse action.

That is my overview, Mr. Chairman. I will be happy to answer any questions the subcommittee has.

ADDITIONAL STAFF FOR ICF/MR SURVEYS

Senator WEICKER. Congress provided $1.9 million in the fiscal year 1985 HHS appropriations bill to fund 45 new ICF/MR surveyors and 12 developmental disability specialists for a total of 57 new staff.

As I am sure you will recall, those 45 new surveyors were determined by Secretary Heckler to be the number necessary in order to increase enforcement of health and safety standards in the ICF/MR. I now am told that you will only be filling 45 of the 57 positions and will redirect the remaining staff to other survey functions.

I have to remind you the 57 additional staff were provided by Congress last year to, and I underline, begin—begin—to address the abso-

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lutely atrocious conditions in institutions for retarded persons. Those conditions were documented 1 year ago in a general overview.

The Secretary's survey confirmed those conditions and next week's hearings on the institutions will show they are continuing. We find people living in filth, in risk of physical abuse, drugs, sexually abused. It is a shame of the Nation.

So I want to know why you are circumventing a clear intent of Congress that you hire 57 additional personnel? Is this your decision, or is it an OMB decision?

Dr. DAVIS. It was my decision. Senator, to redirect 12 people from other survey activities to this effort. It is true that we were given 57 positions, but I was also given an FTE target requiring a reduction of 75 FTE's in order to live with my total——

Senator WEICKER [interposing]. Who gave you this?

Dr. DAVIS. That was an administrative decision not made by us. We now have hired 33 staff and are still advertising for an additional 12. In the face of having to downsize by 75 FTE's, it was my decision to redirect the efforts of 12 individuals involved in other activities to this survey effort. We are committed to devoting 57 staff to address conditions in ICF's/MR. We have been working very vigorously this year, and I think our record will testify to that, Mr. Chairman. We have been out to inspect conditions. I have personally been out to several sites, including, particularly, some of the most egregious facilities in New York State. I have met several times with individuals in the Governor's office in several States and indicated to them our serious intent to continue to survey.

In one or two cases, we have been monitoring facilities on a monthly basis. So I believe the record indicates we are, indeed, not only aware of your concern, but share equally that concern. We are monitoring and will continue to do so.

Senator WEICKER. I have a feeling by the time the hearings on institutions, which will take place on Monday, Tuesday, and Wednesday of next week, are over, the Nation is going to be pounding on your doors, and I think that you better come up with a good answer; indeed, all of us better come up with a good answer. The testimony at least that I have seen that will be presented is absolutely shocking. Nobody is going to listen to what David Stockman's argument is when they hear that testimony. No human being anywhere in the world, much less in the United States of America, should have to live under those conditions.

PROPOSED ICF/MR REGULATIONS

I received a letter from Secretary Heckler dated March 4 in which she stated that the proposed ICF/MR regulations, which have been in the works for several years now, "have entered the departmental clearance process."

Do you have an estimate of when these regulations will be issued, and can you give us any indication of how the regulations will deal with the issue of active—active—treatment for residents of ICF/MR's?

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Dr. DAVIS. The proposed regulations are in departmental clearance. We are aware of the need to expedite this review, and we certainly will do so in a very timely fashion. I think you will find that these regulations strengthen our commitment to the active treatment process. Specifically, they identify more clearly various elements in that process which can be measured and determined to be taking place.

Senator WEICKER. How long has it been since these regulations have been in the development process? Three years, at least. You have no idea as to when they are going to be issued?

Dr. DAVIS. I cannot speak to an exact date; no. The regulations will undergo an expedited review at the Department. We did spend time working with the various provider groups and others who represent the individuals who are in these institutions. There was, therefore, widespread discussion before we actually put pen to paper and wrote the regulations. We have gotten some very good replies from the outside world, and I think that is a very important part of that process.

Senator WEICKER. Senator Harkin.

AREA WAGE INDEX

Senator HARKIN. Thank you very much, Mr. Chairman. Dr. Davis, many of us have been eagerly awaiting for some time now publication of the report on urban and rural wage indices requested by the Congress last summer. I would like to review with you the delay in receiving this report.

The main issue confronting rural hospitals in my State is the lower reimbursement level they are receiving under Medicare's prospective payment system. Although Congress mandated there be separate urban and rural rates for hospitals under Medicare, the way in which the Department of Health and Human Services has implemented the program has unfairly penalized rural hospitals.

In its regulations to implement the prospective payment system, HHS chose to use wage data from the Bureau of Labor Statistics in developing the urban and rural DRG rates for hospitals.

Urban and rural hospital administrators pointed out the fault using BLS data for this purpose. For example, BLS data does not include part-time employees on whom rural hospitals rely heavily. As a response to the outcry from rural hospitals around the country, the Congress wrote into the Deficit Reduction Act of 1984 a provision that requires the Secretary of HHS to revise the wage indices used in calculating the DRG payments and make adjustments in the funding received by all hospitals in the country retroactive to October 1, 1983.

Moreover, the Congress mandated that all such changes must be budget neutral. Thus, some hospitals would receive additional payments while other hospitals would owe the Federal Government additional money.

This report upon which the funding adjustments were to be made was due to Congress in August 1984. The Secretary has made repeated promises to me and to other Members, to committees and to subcom-

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mittees, that the report would be provided. Most recently, she promised it by mid-March. Mid-March has come and gone, and the report still has not been published.

I am disturbed by this continued delay in the publication of this report because, as you know, this report is only the first step in correcting the problems faced by rural hospitals in this country.

After the report is published, HHS must develop and publish regulations to implement the findings of this report, a lengthy process in itself. The longer this whole business takes, the longer hospitals in my part of the country will be operating with inappropriate reimbursements from the Medicare Program.

So I have some questions to put to you this morning to find out when this report will be published and, more importantly, to learn how you plan to proceed with any reimbursement changes that are necessary.

First, I want to ask straight out when are we going to receive this report?

Dr. DAVIS. I expect that you will have the report at the end of this week or the beginning of next week.

Senator HARKIN. At the beginning of next week. Is that for certain now? We had mid-March; we had the end of the year; we have had all kinds of dates. Absolutely?

Dr. DAVIS. It has just about finished all of its administrative reviews.

Senator HARKIN. When is the first of next week: Monday?

Dr. DAVIS. Close of business Monday.

Senator HARKIN. Close of business Monday. Then first thing Tuesday morning, I will have it in my office.

Second, will you be providing the Congress—that is us [laughter] with all of the supporting data that you have collected and analyzed, including the results of the two or more audits that the department has conducted on this matter with this report?

VERIFICATION OF WAGE DATA

Dr. DAVIS. The report itself does not provide backup documentation in terms of what was found in the audits. But let me review what we did do in that area.

You spoke about the audit review. The Department has also been concerned about the amount of time it has taken. I would like to point out that, when we initially prepared the area wage index, we had no data in-house. We had to use data from the Bureau of Labor Statistics.

Once individuals from the hospital industry brought to our attention that there was a problem, we formed our own task force and identified questions that needed to be asked and the data to be obtained. We then proceeded with a survey. Unfortunately, because it was a voluntary survey, we did not get complete compliance from the hospital industry, and found ourselves without a complete sample survey in July of last year. So we had to go back again and have a much more vigorous campaign. Some of us personally called some of the hospitals. We also en-

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listed the support of the various State hospital associations in order to get a sufficient amount of data in-house for a 90-percent sample or above which we believed was necessary to develop a new area wage index.

Without this effort, we would have had a data base that was just as flawed as that used in the BLS wage index. When the data collection was completed, we did do some initial developmental work on it and found some very wide variations.

Because of the concern that the Secretary expressed regarding the possibility of some significant adjustments, we felt it was necessary to go out and audit a sample of the hospitals. I believe we decided in January to do audits using both our resources and those of the Office of the Inspector General——

Senator HARKIN [interposing]. Excuse me for interrupting. How many audits were done?

Dr. DAVIS. There were a total of 63 the first time and an additional—I will have to check, and we will have to give you——

Mr. SCOTT [interposing]. Senator, a total of 173 audits were done.

Dr. DAVIS. I think that is the number, but I will provide it for the record. I know the first sample was 63, and then we went back with a second sample to correct some of the aberrations. I think that proved to be a very wise move because we found some problems.

[The information follows:]

On January 17, 1985, HCFA and DHHS' Office of the Inspector General [OIG] initiated an audit of key data elements from the survey reports of 173 hospitals. Based on the preliminary results of this limited scope audit, either the reported wages or hours worked for 139 providers were revised. The corrected records were made a part of the survey data base.

AUDIT REPORT

Dr. DAVIS. We are now in the final clearance process on the audits, and will soon have a report. I had hoped to have it before I arrived here today. There are just a few minor changes that need to be made.

Senator HARKIN. Basically what you said is you have had to get independent data?

Dr. DAVIS. That is right.

Senator HARKIN. You got the data in?

Dr. DAVIS. That is right.

Senator HARKIN. You analyzed it to show there were going to be some significant—your words—"significant adjustments?"

Dr. DAVIS. That is right.

Senator HARKIN. And, therefore, you said because these adjustments were so significant, we have to go out and do independent audits?

Dr. DAVIS. To make sure the reporting was correct.

Senator HARKIN. You did 173 individual audits of this data?

Dr. DAVIS. I would have to go back—I know the first sample we did, sir, was 63 audits. The second sample may have been 110 audits.

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ADJUSTMENTS TO THE AREA WAGE INDEX

Senator HARKIN. Can you tell us if the audits have shown that there still will be significant adjustments?

Dr. DAVIS. There will be some significant adjustments, not quite as drastic as there would have been had we not gone out and corrected some of the data reported. I think any time when you have a budget neutral situation, as we do have, and you are going to make adjustments, taking money away from some, giving it to others, those who have it taken away will certainly view it as a significant adjustment.

Senator HARKIN. Again, I want to ask you, will the data you collected be available to us, the backup data?

Dr. DAVIS. I certainly would be happy to check with the Secretary and would recommend it. We have no reason not to share it.

Senator HARKIN. I would like to have the first budget data come in, and I would like to see the results of the audits, too.

The American Medical Association News, February 22, 1985, reported that this "Area Wage Index Report" would provide very favorable findings to rural hospitals in the country. According to the article, about one-half of the Nation's rural hospitals will be getting more money under the Medicare prospective payment, while the other one-half will be getting the same or perhaps a little less than they now do.

Moreover, these findings have been validated by HHS audits of 64 hospitals. Or is it 164 audits?

Mr. SCOTT. Two levels, Senator. We did the initial group of audits, and then, based upon the information that came in, the Secretary decided she wanted to do a second group of audits.

Senator HARKIN. It is more than 64?

Dr. DAVIS. That is right.

Senator HARKIN. Can you say whether or not this finding by the American Medical Association News is correct or not?

Dr. DAVIS [interposing]. I cannot truly say because they were looking at the report before the second audit sample had been done. It is always dangerous to deal with documents that are not totally verifiable.

Senator HARKIN. Another thing that is dangerous is for us to accept the report without seeing what the initial findings were and what the audits were.

Dr. DAVIS. I do not have any problem with sharing that material with you.

Senator HARKIN. I would like to see it.

Dr. DAVIS. That is fine. We are not trying to hide anything. You will find that, where there was significant misunderstanding in terms of reporting, the situation has been clarified. Some changes have been made, primarily in some of the wider ranges.

IMPACT OF THE REVISED AREA WAGE INDEX

Senator HARKIN. My understanding is you did the second audit of the findings in the initial area of wage index report, in which you examined the data from 110 hospitals, in which DRG's were changed by 10 per-

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cent or more. Again, can you tell us what the finding of the second audits were; will changes in the data of the 110 hospitals affect the rest of the hospitals in the country?

Dr. DAVIS. Whenever you find that there was a substantial difference in terms of reporting and make corrections because your audit data is more valid than what was reported, then, yes, there will be some minor adjustments. Whenever there is a ratio, an index and you make a correction, then there is a slight change.

Senator HARKIN. Suppose the wage index for a hospital went up by 2 percent. Would this mean an increase in reimbursement to the hospital?

Dr. DAVIS. Yes; it would.

Senator HARKIN. Are you working on a formula now to make adjustments in reimbursements to hospitals which are found to have higher wage indices?

Dr. DAVIS. The formula is really the wage index itself. Once you get an index value for each individual area, then it is applied when you calculate the prospective payment computations. You take your average payment to a hospital and use the index to adjust it.

Mr. SCOTT. The area wage index permits an adjustment to the Federal payment rate. The Federal payment rate is generally more complicated than I can handle, but it is comprised of a regional component and a national component. The labor portion of the Federal payment rate is adjusted by the wage index. Once adjusted, the Federal payment rate is combined with the hospital specific portion used during the PPS transition that you created. This total is then multiplied by the DRG in the particular case.

We do not need to change the formula. The formula would stay the same. Improved or new wage index values will simply be substituted for the old values.

Senator HARKIN. I understand that. I guess what I was getting at, since it has to be budget neutral, there are losers and there are winners.

Dr. DAVIS. That is correct.

RETROACTIVITY OF ADJUSTMENTS

Senator HARKIN. What kind of formula are you going to have for the losers? Is it going to be a lump-sum payment or will it be replacement over a period of time or some other method? If the rural hospitals who have been unduly penalized over this period of time are going to receive higher reimbursements, you have to take funds from someplace else. Moreover, this has to go back to October 1983.

My concern is if you stretch repayments out over 5 years or 10 years, then you might as well kiss some of these rural hospitals goodby because they will have been hit so hard by this policy.

What I am asking is how are you going to implement your findings: will it be a lump-sum payment?

Dr. DAVIS. That has not been decided, sir. I think you have to recognize there are some very major swings both in payments to as well as payments taken away from institutions, and all of that has to be bal-

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anced in terms of the impact on the total system itself. Many of the rural areas may or may not be surprised. It won't be the answer for everything.

Senator HARKIN. That is why we want the supporting data on this. These rural hospitals are concerned about when they are going to get their appropriate level of reimbursement. I can tell you right now, some of them are in a situation that if they don't get these reimbursements by the end of this year, they are done. This is especially unfair because Congress mandated that changes be made. If these reimbursements are not made in a timely manner, then the will of Congress is going to be thwarted.

So I will be interested in seeing your report next Tuesday and the accompanying data, the initial data and the audit data to back it up. Thank you, Mr. Chairman.

Senator WEICKER. Thank you, Senator. Senator Andrews.

VALIDITY OF AREA WAGE INDEX

Senator ANDREWS. Mr. Chairman, my concern, and it is nice and it is refreshing if we are going to get this report on Tuesday, but, Mr. Chairman, might I suggest to you that since this has taken so long and since the report becomes available so conveniently a couple of days after we have our hearing, that we ask Dr. Davis and her people to come back so we can reexamine after we see what this report is.

I am a lot more concerned about the quality and the accuracy and the justification of what is in this report than I am in its lousy timeliness, and I get darned sick and tired of having us as a committee, Mr. Chairman, being kept in the dark by having this kind of a report conveniently come out just after Dr. Davis is here, so that we can't question her on the substance of some of the idiotic things that are taking place out there, some of the directions that you have been giving in the field and the total nonresponsiveness you have had to the problems we have got.

Senator Harkin brought out some of the things we have been talking with you about in this committee for a couple of years. You arbitrarily and capriciously name hospitals in a major town in my State, rural hospitals, not as large as urban hospitals. You arbitrarily tell that hospital that it is only going to get 80 percent as much for a procedure as another hospital does in a town that is smaller with an airbase and all of that.

We ask you the question, you come up very politely to meetings and all of this and you say, well Congress mandated that. Congress did not mandate that type. We told you to go out and come up with a worthwhile program, and now finally 2 years ago the thinking you are going to come up with a report after—after—the fact. Mr. Chairman, I would suggest that after we get this report and after we see the methodology that went into it that we reconvene the hearing with Dr. Davis and her people so we can find out just where we are going.

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I say that for a couple, three reasons. As I mentioned earlier, we have been involved in the prospective payment system for over a year. We have not had any data presented to us to see if it is working for both the hospital and the patient. I have read reports where hospital costs have decreased and so have admissions, but can you give us any indication, Doctor, on what the effect is on the patient?

Dr. DAVIS. Yes, sir, I can.

Senator ANDREWS. Sure; what?

Dr. DAVIS. Let me go back first and make a couple of comments. I will be happy to come back and appear——

Senator ANDREWS [interposing]. I think it will be a lot more worthwhile.

Senator WEICKER. Let me accept the suggestion and add the accompanying comment. It is the suggestion of the Senator from North Dakota that we will have Dr. Davis back here. These hearings go on for another several weeks. So it is not a question that time cannot be found. It can be found; it will be found to respond to both concerns expressed by Senator Andrews and Senator Harkin, and it will be done in the sense of a formal committee setting. So Dr. Davis already indicates she is going to do that. It will be during the normal course of the Labor-HHS hearings.

Senator ANDREWS. We have plenty of time because we are going on before we mark up the bill.

Senator WEICKER. It really makes a lot more sense for you to have the material in front of you to ask the questions, provide questions. An opportunity will be given to Members of the committee.

QUALITY OF CARE UNDER PROSPECTIVE PAYMENT

Dr. DAVIS. If I can answer your question regarding impact of the PPS on hospitals and, especially, on the beneficiaries, as a result of the first year and a half of its operation, we have been monitoring this system very carefully. While there has been a reduction of approximately 1 day in the length of stay in contrast to those hospitals that have not been under prospective payment, all hospitals have been reducing their length of stay. It is just simply those under prospective payment have been more aggressive.

This is being done, I believe, through better monitoring of what is going on in treatment modalities during the time the patient is in the hospital. By that, I mean, hospitals are very frequently assigning a patient care coordinator, a primary nurse, who has the responsibility for making certain that the care plans are coordinated; that nobody forgets to carry out certain treatments the night before procedures are to be done so that they are not delayed; that there is a much more coordinated effort regarding these plans; that there is patient and family education as well as early planning in the event that the individual family member may have to go home or be referred to a skilled nursing facility.

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We are finding an improvement in the continuity of care that is going on for the patient in the hospital. We have been tracking a number of aspects in this regard. For example, we have been monitoring whether or not there has been an increase in the number of readmissions because it has been alleged that one way to maximize reimbursements would be to deliver less care, send the patient home and bring them back in again. We have not seen that happening, Senator.

About 1.3 percent of all admissions reviewed are readmissions. By most individual medical standards, one can assume that a certain number of these readmissions result from problems unrelated to the patient's first hospital experience or, in some cases, reflect no diminution in quality but are simply due to clinical problems. We are monitoring this situation. I think it is important to recognize that there has been no change in mortality rates. We are monitoring a number of quality factors.

We do know that there has been some enhancement in the quality of care as a result of specialization in certain high cost procedures such as coronary artery bypass surgery and those which are more neurosurgical in nature. We have observed that, where there are four or five hospitals in a given area, they are now apt to combine their resources. Rather than each offering a limited number of those procedures, we are finding that hospitals are pooling resources on their own with one hospital focusing on a specific procedure.

A Public Health Service study indicates that, when hospitals do a high volume of such high technology procedures, the respective mortality rate is reduced. It found there was a 13-percent decrease in mortality rates when a high volume of such procedures are done because the hospital staff are more trained. They can recognize minor signs and symptoms.

So I think we are finding improvements in this area as a result of the specialization. By all the indicators that we currently use, it appears there has not been a decrease in quality. However, we have a very aggressive monitoring program, both through the computerized checks done by our intermediaries, as well as with our peer review organizations.

Peer review organizations have five mandatory areas that they must review for quality. They monitor a random sampling of admissions as well as some cases that are specifically targeted. Where there is a potential for abuse, as in the pacemaker area, all admissions are reviewed. In addition, all transfers and all readmissions are reviewed. About one-third of all admissions are being monitored under the peer review system for appropriateness of care and quality.

AREA WAGE INDEX

Senator ANDREWS. And that is very true. Of course, it is one of the things that we very definitely want to keep on track. Dr. Davis, a minute ago earlier on you said that all of this, all of your procedures, all of your reasons have to be valid. I salute that. Nobody is going to

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disagree with that. But I cannot help getting back to what my colleague from Iowa pointed out and what I mentioned earlier on, and what this committee has visited with you about for, lo, these many months, many years.

In being valid, how do you justify for one hospital that has exactly the same labor costs as another one does, it is 100 miles away from the other one, same size community, that you, the Government, are only paying them 80 percent as much?

Now, I realize that out there you say, well, it is a combined metropolitan area and all of that, but you know the case that we have gone with, and that is why I am much more interested in what went into these findings than the date we are going to get it. That is why we cannot really do a good job of questioning you until we find out what kind of supporting evidence, what kind of validity, to use your word, has gone into it.

So we would like to have the justification accompany that report. How can you take town *X* that has the same labor costs and all the rest in the State of North Dakota and the State of Iowa and because someone put into the regulation something, then come down and say, well, Congress directed us to do this when obviously it flies in the face of all kinds of good judgment.

I would also suggest to you, and you brought this up when you mentioned the fact we have to be more aggressive in making sure of the quality of medical care, that is very true, but then let me ask you how you can justify, for instance, in a cataract procedure—we have a group down in Hettinger, which is out in the middle—a very rural area. It is 150 miles away from hospitals to the south and southwest, and it is probably 100 miles from hospitals in the northeast.

My colleague, Senator Chiles, was out hunting pheasants. Hettinger is about 70 miles south of where we were that day, and these are wide-open spaces. They have a fantastic team of doctors, well trained. They do a great job, and they are wise enough to know the procedures that they can do and the procedures they cannot. They do a good job, for instance, in cataract and a number of other things.

Senator CHILES. Pheasants are awfully smart out there, too. [Laughter.]

Senator ANDREWS. You bet. And that wasn't because we are good shots. My colleague from Florida is a dead-eye. He can hip shoot a pheasant at 150 yards and do it well. I can testify to that on a totally bipartisan basis. [Laughter.] I want him on my side, particularly if he is shooting live ammunition.

In this discussion that we are having, the Federal Government has now come out and for a cataract procedure, they will pay the Hettinger group in the neighborhood of $670. If the cataract procedure is done in Bismarck—and I understand the wholesale cost of the lens is over $600—if it is done in Bismarck, ND, where they have very competent surgeons as well, the Federal Government pays $1,100 or $1,200. If it is done in Chicago, they pay in the neighborhood of $2,400.

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You know, this kind of boggles the imagination. If the doctors in town *X* are competent and if they are not, they should not do the procedure, why then does the Federal Government, who on the one hand is doing what you say, making sure that they are competent, pay one-third as much for a procedure in a given town than they do in another, how can we maintain this kind of hospital care, this kind of medical care in the rural areas if you are going to say that a procedure gets paid three times as much in a large metropolitan area as it does out in the relatively rural areas?

URBAN VERSUS RURAL RATES

Dr. DAVIS. Perhaps, Senator Andrews, I can go back and explain how this happens because it is not capricious and arbitrary at all.

When Congress mandated we should have rural and urban rates, we decided to use standard metropolitan statistical areas as the basis because that is what we had been using for a number of years. We collected historical cost data from the hospitals that were then in the rural areas, as well as from hospitals inside the urban areas. When the data was summed and divided to get a mean value, we found an 80-percent differential between urban and rural costs. The urban and rural rates were based on the actual costs of hospitals operating in those areas.

Senator ANDREWS. We cannot reconstruct those numbers, Dr. Davis, however, and when we ask you for the specifics of saying why these numbers are different between a given hospital and another, they cannot reconstruct it other than to say it is supposed to be 80 percent because of something.

Senator HARKIN. Will my colleague yield?

Senator ANDREWS. Sure, I will be glad to yield to my friend.

Senator HARKIN. This just doesn't make sense. In every case I examined, just in Iowa, in the urban areas, where you have a large city like our capital of Des Moines, we have several hospitals; they have all combined and they have for years, in terms of their purchasing and everything else. They purchase in huge quantities and always get a lower price. Now you take a smaller hospital 80 or 100 miles away, they do not get that opportunity to buy in large quantities; they have to pay a higher price. In no case have I ever seen where the prices paid by these urban hospitals have ever been more than the rural hospitals. They have always been less. And yet the reimbursement rate is just the opposite.

Senator ANDREWS. Doctor, what you were pointing out 1 minute ago, if I understood you correctly, is you went back and you examined the cost base for these.

Dr. DAVIS. Yes, sir; we used data supplied from the 1981 cost reports.

Senator ANDREWS. Then if you can go on and finish that, I have the followup to that statement because I think it is very intriguing.

Dr. DAVIS. I think I can clarify this for you. We had data that came in and was aggregated for the rural hospitals. We developed our data base from 1981 cost data. I should point out two things. We are phas-

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ing in a national rate because it makes more sense to pay one rate nationwide than to have the variations that are around the country. But this year, as we move to the third year of the phase-in, 75 percent of the PPS payment will be based on the Federal portion, composed of 37.5 percent of the regional rate and 37.5 percent of the national rate. The remaining 25 percent of the PPS payment will still be based on the hospital's own historic costs.

In addition, as you mention, Senator Harkin, hospitals can bulk purchase and, indeed, many do, not only in the large urban centers, but I think increasingly large numbers of rural hospitals are banding together in consortiums to take advantage of group purchasing and group service contracts.

I should also note that 80 percent of the Federal rate is modified by the area wage index which reflects a significant differential between urban and rural costs in some areas. That, too, makes a difference.

Senator ANDREWS. Doctor, we beat that old dog to death. You come up and tell me in Minot, ND, there is a different wage index than there is in Bismarck, ND. The Federal Government says there is. But if you go out and you talk to the nurses and you talk to the mechanics and you talk to the people who work in the pharmacy, they get paid exactly the same wage in Bismarck, ND, as they are paid in Minot, ND. Yet, the Federal Government has this magic figure, and that is why we want to cross-examine you after you come in on this because what you say is simply not true. The wages of people in the one town are precisely the same as people in the other.

As a matter of fact, a little higher in Minot because Minot has got a Strategic Air Command base 5 miles out of town and has 5,000 military there.

Dr. DAVIS. Senator, I will be happy to walk you through all the justifications, and I think it is a complicated process. We used actual cost data. I have no problems regarding its justification. I will be happy to have my technical people and myself walk you through any——

Senator Andrews [interposing]. We have walked through them before. We would like, as a matter of fact in preparation for the hearing, and I don't want to take any more time of my colleagues on this issue here, show us the specifics where you got the figures from the actual towns involved rather than someplace else, and that would be most helpful.

I could not be happier that you are moving toward a national rate on a procedure, but is it not, indeed, and, in fact, true that a procedure in Hettinger, ND, may well be paid one-third as much for the same procedure in Chicago at this time?

Dr. DAVIS. In fiscal year 1985 the PPS payment is based on 50 percent of the hospital's own historical cost base and 50 percent of the combined regional/national rate.

Senator ANDREWS. But what you have done is picked up, as you said 1 minute ago, the average cost in the past, and if the rural hospital out of concern for the patient because of the rural work ethic was charging less for a procedure some time ago, and the big city, because of the

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way of repayment being insurance and all the rest, was charging all the traffic would bear, you go out on past history and the gougers come out looking darn good, and the people who were doing it at a reasonable rate really get it in the neck, isn't that essentially true as the formula now exists?

Dr. DAVIS. But that is why we are phasing in one national rate, Senator Andrews. It was Congress who decided we should do a phase-in approach over 3 years.

Senator ANDREWS. If you can give us the phase-in rates and what we can estimate on down the line, that will also be helpful for the committee to look at.

FEDERAL MEDICAL ASSISTANCE PERCENTAGE [FMAP]

Finally, in our committee report last year, we directed you to work with various agencies. In fact, the language is this:

> It has come to the attention of the committee that the formula used to calculate the Federal medical assistance percentage for the States is at least 2 years old by the time Federal funds allocated under the formula actually become available to the States. In addition, a few States, especially rural ones with large per capita farm income, have occasionally experienced extreme swings in their matching rates. There is no clear reason for this, but the committee understands one reason may be the difficulty in estimating farm income.

We go on to say:

> The State of North Dakota has been the most severely affected by this phenomenon. The impact of these swings has been exacerbated by the long period between the time the formula is calculated and the time the matching funds are used.
>
> The committee, therefore, directs the Health Care Financing Administration to work with the Department of Agriculture, the other appropriate agencies within the Federal Government, and the appropriate interest groups to improve this situation. In addition, the committee directs the Department to look into the possibility of updating the data used in the formula in a more timely manner, updating the formula calculation on an annual basis, and developing alternatives to minimize the volatility in the swings experienced by the States with large per capita farm income.

What have you done, Dr. Davis, to fulfill that directive from the committee?

Dr. DAVIS. Our actuaries are now developing a State-by-State analysis based upon some of those recommendations. We are exploring the possibility of updating the formula annually and are also looking at averaging the per capita income over shorter and longer periods of time. However, I must mention that the resolution of both the timeliness and volatility issues is a very difficult problem.

Senator ANDREWS. We understand that, Doctor, and that is why we put this in the report. What you are telling us is that you do not have the response to that directive at this point in time.

Dr. DAVIS. No, sir, I do not. We are working on that. Once the actuaries have prepared that data, we must spend some time in further analysis of it.

I should also point out that any changes, whether technical or substantive, would require legislation because the FMAP calculation methodology is spelled out extremely precisely in sections 1905(b) and 1101(a) of the Social Security Act.

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Senator ANDREWS. But would you have that response to that directive when you come back? Again, we do these on an annual basis, and we put a directive into the report in 1 year's appropriation, we almost have to have your response by the time you come back the next year or we just don't get the answers we are looking for.

Dr. DAVIS. Senator Andrews, I cannot say with any degree of certainty I will have that by the time we come back.

Senator ANDREWS. Then I guess what I have to do is ask you to make a dead level best effort to have it because, again, it is a lot easier to be talking about facts than to be talking about rumors and trying to compare apples with oranges.

Dr. DAVIS. I understand that.

Senator ANDREWS. The needs of the Nation are that we conduct these hearings based on factual evidence. So it would be very helpful. Thank you, Mr. Chairman.

Senator PROXMIRE [presiding]. Senator Chiles.

FLORIDA HMO DEMONSTRATIONS

Senator CHILES. Thank you, sir. The department published final regulations regarding the Medicare participation in the HMO organizations in January. During that period the regulations were being developed, there were a number of demonstration projects. Several thousand Florida Medicare beneficiaries were enrolled in these HMO's. All of the members of the Florida delegation heard complaints from Medicare beneficiaries regarding the care they were receiving as well as serious problems getting timely Medicare payments. Because of these complaints, GAO evaluated payment problems in four Florida demonstrations. That report was released to Congressman Larry Smith 2 weeks ago.

GAO found an error rate for processing Medicare claims for HMO members of 30 percent. The billing system does not seem to be able to tell who is a member of an HMO and who is not. What that means is that Medicare will still pay bills for an out-of-plan physician or hospital contract for a beneficiary who is a member of an HMO at the same time that it is also paying the HMO for that beneficiary.

That came to over $700,000 in duplicate payments just in the small Florida sample looked at by GAO. It could also mean, and this is worse, that a Medicare beneficiary who is a brand new HMO member, or has just switched out of an HMO plan, cannot get any Medicare bills paid. The computers say he is still in an HMO for 1 month or even 2 months after he no longer is. If he gets sick during that period and has to see a doctor or go to a hospital, all the bills are denied. In effect, he has no Medicare coverage at all and has to pay the bills himself.

It seems to me that these are administrative problems that absolutely have to be solved before any more HMO's are signed on under the new regulations.

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What is being done to remedy this situation, and do you have a definite timetable?

Dr. DAVIS. Yes, Senator Chiles. It is unfortunate that the GAO, for whatever reasons, chose not to share their report with us before releasing it. Many of the problems we had known about and had already taken some very vigorous steps to correct and, indeed, they have been corrected. Let me report on a number of those issues.

You raise the issue that there have been billing problems due to a lag time in processing data and that some individuals were allegedly not getting their bills paid. It is true that there was a lag time for a while, primarily as a result of having to move on to the Social Security Administration's computerized system. We have been working vigorously with an internal task force and the Blue Cross in Florida, and we are now able to issue letters to individuals so that, if they do disenroll, they will have immediate access to coverage. As of April 1, our response time, in terms of integrating data into the Social Security Administration's computerized system, is now 5 days after the first of the month. As of May 1, we will actually be able to be on line as of the first of the month.

I believe we have that problem totally taken care of and had GAO asked us about it, we would certainly have informed them of our progress in this regard.

With respect to the error rate, we have asked for the specific data that GAO referenced so we can go back and cross-check it against our figures. We have been talking with the team in the Blue Cross office and our figures do not reflect the same error rates. We will be happy to review each and every error rate.

Senator CHILES. Thirty-percent error rate is a tremendous error.

Dr. DAVIS. That is true; if that was the case, the HMO would not pass our performance objectives. That is why we need to see the data GAO based its judgments on in order to verify it. We are working now to get that data.

HMO MONITORING

Mr. SCOTT. Excuse me, Senator, if I could, one of the other concerns you expressed had to do with quality, which, when we get down to it, is much more important than the mechanics we have to work out to pay the bills. I think we have been as interested in the quality issue as anybody has been. Our peer review organizations, which have started out primarily to review hospital inpatient services, will, under an anticipated expansion of their role in ensuring quality health care in this country, review HMO services. We are working hard with the physicians from HMO's——

Senator CHILES [interposing]. We have a 40-percent disenrollment rate in Florida. That is 40 percent of the Medicare beneficiaries who sign up to join one of the HMO's change their minds and get out again and most who get out, some 70 percent stay for less than 2 months. That has got to be saying something about the quality of care.

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Dr. DAVIS. I think those rates need to be validated, as to the time-frame they reflect and where they occurred.

Our data does not look exactly like that. It is true that problems sometime occur in the initial start-up phase of any HMO. Particularly, in some of the demonstrations in Florida, when they first started several years ago, we learned that you must not only give written instructions but must also verbally explain to the enrolled beneficiaries that they cannot seek usual care under the fee-for-service routine.

We very quickly established new guidelines and each of our HMO's must provide verbal explantions of the process and follow through with written instructions so that, before beneficiaries enroll or at the time of enrollment, they can read the material and understand the limitation.

Senator CHILES. I wish you would look into it and let me know how you relate to that. I want to know exactly how you are set up to evaluate standards of care and protect the beneficiary interest.

Dr. DAVIS. There is a quality control system being developed. We worked this last weekend with the HMO industry and some of the peer review organizations to establish some new guidelines.

Senator CHILES. I want to see the program work. I support the concept, and the department seems to have an even bigger stake since you continue to propose to turn the Medicare Program into a voucher program.

But as the Florida situation shows, it is a big leap from providing Medicare beneficiaries with opportunities for participation in well-established HMO's to a full-scale program without knowing what you are doing.

I can just see all the storefront clinics applying for new status as HMO's under Medicare. It is a good deal. I can get hundreds of dollars per month, guaranteed, for everyone I sign up. And right now it sure looks to me the message is that I would not even have to worry about anyone looking over my shoulder to make sure that I took care of patients the way I said I would.

Dr. DAVIS. No, Senator Chiles, we take our responsibility regarding quality of care very seriously. I think the whole HMO growth movement would fail if we did not ascertain they delivered high-quality care. That has been one of our major concerns.

We do have a review process in place. Indeed, each of our demonstrations must be re-reviewed before they go live as an actual HMO under the new regulations. They have just been through this review process and as of April 1, the majority of our demonstrations will be converted to actual status, at which time they go through another review process.

Mr. SCOTT. In addition, we put a number of things into the regulation we hope would help prevent the creation of a storefront HMO.

We have confidence in the marketplace and consumers. We are requiring the HMO's not to be strictly Medicare and Medicaid HMO's. We think that, in order to qualify to take care of our patients, HMO's are going to have to prove in the market with the regular health in-

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surance patient that they can provide reasonable care at a reasonable price.

Senator CHILES. I hope it is.

Mr. SCOTT. Some of us have our careers on it.

Senator CHILES. I have never seen anybody yet bet their career on anything around here.

FISCAL YEAR 1985 TARGETED ASSISTANCE

Senator CHILES. Mr. Hawkes, in the conference report to the 1985 continuing resolution, Congress directed your agency to maintain funds for refugee and entrant assistance in the 1984 levels. The report specifically instructed that you, and I quote, "not reduce any State or local entity's allotment on the basis of 1984 funds carried over or previously committed."

The report further directed that funds should be expended in a timely and expeditious manner, noting that delays until the third and fourth quarter of each year had been used to reduce the allotment.

When congressional intent is clear regarding the allocation of new moneys for targeted assistance to the States, why does your 1985 projection contain only $10.9 million in new money and $39.1 million in carryover?

Mr. HAWKES. Senator, the 1984 targeted assistance authorization was changed during the course of 1984 from a 1-year to a 2-year appropriation. That was done primarily because the rate of use of targeted assistance funds had fallen far below the anticipated levels.

Currently, the targeted assistance program in place around the country in 20 States and 44 counties is still running principally on 1983 funds. In fact, the money currently available in the targeted assistance program, the $39 million of unexpended funds from 1984 and the nearly $11 million to be added in 1985, will fund the existing program through the second quarter of 1986 for all States and counties and will fund about one-half of those participating throughout 1986.

In interpreting the continuing resolution for 1985, we took into account the moneys that were carried over from 1984 that had not yet been obligated. They were added to $11 million in new fiscal year 1985 funds to come up to the $50-million level of the 1985 continuing resolution. If we had taken the $50-million figure in the congressional language in all new 1985 funds and added the $39 million that was left over from 1984, it would have produced a figure higher than authorized by the continuing resolution.

It is our understanding that the continuing resolution is not meant to increase the level of funds above that expended in any previous year. The continuing resolution does require that no program be reduced as a result of the carryover of 1984 funds and no program has been reduced. As a matter of fact, all programs are funded at least half way through 1986. So we believe we have, in fact, met the intent of the continuing resolution.

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Senator CHILES. Where is this $39 million in carryover funds coming from? What States have not allocated their funds, the funds in their possession?

Mr. HAWKES. Each of the participating targeted assistance States will carry over some funds. The intent of the continuing resolution seems to be to maintain continuity and to continue programs at their current level of operations. That is being done in all participating States well into 1986 with the 1984 and 1985 funds that are currently available.

There is no reduction in any targeted assistance program as a result of ORR's interpretation.

Senator CHILES. My understanding is the States are having to stretch out one fiscal year's funds three quarters into the next year and are falling short at the end of their program years because of this consistent slowdown in the flow of funds by your agency.

Mr. HAWKES. Senator, I disagree with that. At this point, many of the 44 counties participating in the targeted assistance program are closing out their first targeted assistance awards which were made in 1983. There are counties which have carryover fiscal year 1983 funds that they are using to supplement their 1984 awards.

FLORIDA TARGETED ASSISTANCE

Senator CHILES. Florida's total targeted assistance for 1984 was $21 million; $5 million of that still has not been programmed by the Office of Refugee Resettlement.

Mr. HAWKES. All Florida programs are continuing to operate. We have talked to people from the Dade County School District and Jackson Memorial Hosptial and there are no gaps in funding that I am aware of.

Senator CHILES. Maybe it ends up with no gap. Constantly they never get their money on time. They are always running and waiting and waiting. What is the game you play with them that you just hold up your funding?

Mr. HAWKES. Senator, we are not playing a game with Florida. The targeted assistance program has been in place since 1982. Since 1982, $205 million has been appropriated for targeted assistance and Florida has received almost half of those funds.

The programs have been in operation since 1982, and we are attempting to maintain continuity in the State. However, the State consistently reports unexpended funds at the end of each fiscal year. We have allowed them to carry those funds over to the next fiscal year. We allowed the State of Florida to move funds from one program activity to a different program activity. I do not think there have been any delays in the program other than those resulting from attempts on the part of ORR to get additional information on which to justify either the awarding of additional funds, the approval of funds transfer from one program activity to another or the carryover of unexpended funds from one fiscal year to the next. We have tried to be as accommodating as we can in every instance.

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CONSULTATIONS MEETINGS

Senator CHILES. Congress has provided specifically to the Director of ORR the responsibility for consultations between your agency, voluntary resettlement agencies and State and local governments before resettlement of refugees.

Have you established an appropriate system for these consultations, and how many have occurred?

Mr. HAWKES. That directive came in the amendments to the 1982 reauthorization of the Refugee Act. The refugee program is primarily a State-administered and federally funded program. For instance, the Director of ORR is also required by the Refugee Act to provide assistance to refugees all over the country, but we use state welfare agencies and State social service agencies to do that.

The requirement in the law calls for consultations, not less often than quarterly, between voluntary agencies and local governments and other interested parties, so that they may plan their programs and project social service and other needs based on anticipated refugee arrivals in their areas.

That was done particularly because of the large number of refugees who came into the country in 1980 and 1981. We published a requirement in the Federal Register that States set up at least quarterly meetings between those parties. In addition, ORR has paid the costs of those meetings. Recently, however, about 20 States have asked to have the requirement waived, saying they have in place mechanisms that ensure the transfer from organization to organization of enough information to do the necessary planning, and thus have met the intent of the law.

I believe that by requiring those meetings to be held, by participating in some and funding them, we have, in fact, met the intent of the law.

Senator CHILES. I understand you directed this responsibility, you delegated it to the State refugee coordinators. It seems to me if Congress told you they wanted coordination, I don't know why you are delegating it. Maybe we ought to transfer this responsibility to the State Department.

Mr. HAWKES. That would be interesting, Senator.

Senator CHILES. I have another question that I will submit for the record, if I might, Mr. Chairman, having to do with the systems modernization on computer capacities in the future.

DEFENSIVE MEDICINE

Senator PROXMIRE. Dr. Davis, a January article in the New York Times reporting on an AMA malpractice claim study indicated that the total cost of additional tests and treatments that would not have been ordered except for fear of a malpractice suit was between $15 billion and $40 billion—not millions but billions of dollars.

First, can you narrow that range? From $15 billion to $40 billion is a pretty broad range.

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Dr. DAVIS. I have heard reports that it is more in the neighborhood of $15 billion to $20 billion, Senator Proxmire. But, again, this estimate does not strictly have a factual basis. It is very difficult to estimate the cost of defensive medicine because doctors often order additional tests as a protection against a malpractice suit. Therefore, it is really a matter of pure estimation.

Senator PROXMIRE. It is an appalling cost, even if it is only $15 billion or $20 billion. It sounds like a Defense Department program.

Dr. DAVIS. Well, one does have to wonder about the whole issue of malpractice. Of course, the court system being what it is, with awards getting larger and larger, primarily in the punitive damage part, I think it has some degree——

Senator PROXMIRE. Has HCFA taken any steps to deal with this problem other than through the implementation——

PHYSICIAN MALPRACTICE COSTS

Dr. DAVIS [interposing]. As part of our collection of data on physician costs we are obtaining information right now to determine exactly what the increased costs are for malpractice premiums. There is a study going on now that looks at the area of physician malpractice costs in an effort to measure the portion of the overall malpractice costs that is attributable to Medicare patients versus that attributable to non-Medicare patients. It is a difficult thing to tease out.

We are also testing the ability of our contractors to identify claims made through malpractice judgments so that we can obtain better data on this area.

Senator PROXMIRE. I am just asking about the total costs of additional tests and treatments.

Dr. DAVIS. That is right.

INCREASE IN MALPRACTICE INSURANCE PREMIUMS

Senator PROXMIRE. Malpractice premiums must be absolutely astronomical.

Dr. DAVIS. They are rising.

Senator PROXMIRE. My son-in-law is a doctor and tells me his malpractice premiums have gone up to something like $40,000 a year—for one doctor.

Dr. DAVIS. There is variation, of course, around the country. We do know, for example, that, in New York State recently, the premium increases were quite alarming. At least in some specific instances, the rate increase in 1 year was approximately 52 percent. Now, this is based on a small sampling of specific physicians. I think this sample comprised about 2 percent of the physicians. Nevertheless, I think it is becoming an increasing problem for us in this Nation.

Senator PROXMIRE. Dr. Sammons, the AMA's executive vice president, was reported by the Times to have said in an interview, and I quote:

The peer review mechanisms, in our view, definitely need to be beefed up.

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Another unidentified AMA official was quoted as saying:

> We are going to be doing everything we can to get patients into the hands of good physicians. In this age of computers and communications satellites, we should be able to come up with a national data bank on physicians' performance.

Is HCFA making an effort to beef up the peer review organizations and will you be working with the AMA on the issue of physician performance?

Dr. DAVIS. We have been working with the AMA and other medical societies during the initial implementation of our peer review organizations. I am delighted to hear that Dr. Sammons indicated our peer review effort should be beefed up. There are a lot of folks out there who did not think that a few months ago.

I have always been a strong supporter of increasing our peer review surveillance because I think it will improve the quality of care and give us known outcome measures by which we can begin to make some decisions. Not only we, but also the physicians themselves who look at that data can make decisions regarding their practice patterns.

Senator PROXMIRE. Also, as a happy fallout, presumably it could greatly reduce the terrible cost of malpractice suits.

Dr. DAVIS. I believe, sir, when you have a peer review that has established certain protocols of treatment in a given geographic area, this reflects that physicians in that area agree those are the right compliance protocols. If physicians can indicate they are following those guidelines, then it seems to me this would cut down on the kind of malpractice liability that we have seen out there.

There are also some studies that we are doing. We are funding some work relative to a study by Dr. Wennberg, which focused on outcome measures and examined variations in the practice patterns of physicians around the country. One of our peer review organizations is to integrate aspects of Dr. Wennberg's study into its peer review. I think that holds some exciting promise.

REIMBURSEMENT FOR HOSPITAL INTREST EXPENSES

Senator PROXMIRE. I understand the inspector general has found that HCFA could save Medicare and Medicaid about $4.7 billion over the next 5 years by closing a loophole that allows hospitals to earn interest on funds set aside for future capital needs without offsetting this earned interest against interest expenses claimed for reimbursement. Do you have any plans to implement that recommendation?

Dr. DAVIS. I think we have a difference of opinion on whether this would produce a true savings or not. Let me point out one factor. Interest expenses related to operating costs are reimbursed under PPS, and, therefore, can't be reduced by investment income. The inspector general did not take that into consideration.

Second, we believe that if incentives for inded depreciation are reduced, then, when hospitals have a capital expenditure, they might have higher capital interest charges and——

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Senator PROXMIRE [interposing]. That seems to me to be a pretty fundamental difference.

Dr. DAVIS. We are working some of these issues out.

Senator PROXMIRE. I am going to ask the inspector general to comment if he wants to comment. This is a lot of money.

Dr. DAVIS. Yes, it is.

GUILLAIN-BARRE SYNDROME

Senator PROXMIRE. Dr. Davis, one more question. Last week, Dr. Goldstein of the National Institute of Neurological and Communicative Disorders and Stroke discussed the use of plasmapheresis to treat Guillain-Barre Syndrome. That procedure is being used by Froedtert Memorial Lutheran Hospital in Milwaukee and a doctor at the hospital has estimated it has saved millions of dollars in hospital expenses. However, because the treatment is so new, insurance is just starting to cover its costs.

Does HCFA recognize this as an appropriate treatment for Medicare and Medicaid purposes?

Dr. DAVIS. My recollection at the moment is that I do not think we do, at least under Medicare. I will have to submit that for the record.

Senator PROXMIRE. You are looking into that.

Dr. DAVIS. Yes.

[The information follows:]

Medicare does not cover plasmapheresis for the treatment of Guillain-Barre Syndrome [GBS]. However, the question of whether Medicare should cover this treatment for GBS was presented to the HCFA physicians panel for review on March 12, 1985. The panel referred it to the Public Health Service [PHS] with a request for an assessment of the safety and effectiveness of plasmapheresis in the treatment of GBS. When the PHS has completed its evaluation, it will make a formal recommendation to HCFA with respect to the safety and efficacy of the procedure, and HCFA will then decide whether the procedure should be covered by Medicare.

With regard to Medicaid, each individual State decides whether to cover plasmapheresis for the treatment of GBS. If a State pays for treatment, the Federal Government will pay its matching share.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator PROXMIRE. I have some other questions for the record. I want to thank you very much. I am sure the chairman would want to do the same.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

ICF/MR AND DEVELOPMENTAL DISABILITY SPECIALIST POSITIONS

Dr. Davis, Congress provided $1.9 million in the FY 1985 HHS appropriations bill to fund 45 new ICF/MR surveyors and 12 developmental disability specialists for a total of 57 new staff. As I am sure you recall, those 45 new surveyors were determined by Secretary Heckler to be the number necessary in order to increase enforcement of health and safety standards in the ICFs/MR.

I am now told that you will only be filling 45 of the 57 positions with new staff, and will "redirect" the remaining staff from other survey functions.

Question. Why are you circumventing the clear intent of Congress that you hire 57 additional personnel? Were you unable to get approval from OMB to hire that number?

Answer. It was my decision to redirect 12 people from other survey activities to this effort. It is true that we were given 57 positions, however, it was more expeditious to redirect 12 experienced surveyors to this activity. In addition, as HCFA streamlines its organization, staff will continue to be redirected to high priority initiatives.

PROPOSED ICF/MR REGULATIONS

Dr. Davis, I received a letter from Secretary Heckler dated March 4 in which she stated that the proposed ICF/MR regulations -- which have been in the works for several years now -- "Have entered the Departmental clearance process".

Question. Do you have an estimate of when these regulations will be issued?

Answer. The draft ICF/MR regulations recently underwent review by components of the Department. Comments that resulted from this review are now being evaluated by staff of the Health Care Financing Administration to determine which should be incorporated and to identify and resolve divergent opinions. Although it is difficult to predict precisely when a Notice of Proposed Rulemaking will be published, please be assured that we are aware of the strong support for modification of the existing rules by members of your subcommittee and within the professions that serve the developmentally disabled.

Question. Can you give us any indication of how these regulations will deal with the issue of "Active Treatment" for residents of ICF/MRs?

Answer. The concept of "active treatment" is scattered throughout the existing standards rather than being presented as a separate requirement. While the "active treatment" approach was useful in describing the roles of the various professionals

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involved in the treatment of the developmentally disabled, it has been difficult for facilities to clearly understand our requirements or for surveyors to evaluate their performance against them. The draft proposed ICF/MR regulations would consolidate "active treatment" requirements and would clearly define "active treatment" as including those interventions that enable the client to acquire developmental, behavioral, and social skills necessary for the maximum possible independence. The proposed rule would specify that all ICF/MR clients must be in need of, and receive, active treatment.

PROTECTION AND ADVOCACY TECHNICAL ASSISTANCE

Last fall Congress reauthorized the Developmental Disabilities Act (P.L. 98-527). Among other things, this Act mandated that protection and advocacy groups within each State are to receive the ICF/MR survey reports and plans of corrections for deficiencies within 30 days after completion of those reports and plans. Since this is the first opportunity that these groups have had to review these documents, I believe they could benefit from technical assistance from the Health Care Financing Administration (HCFA) in interpreting their contents.

Question. Would you be willing to have each of the HCFA Regional Offices conduct a one-day technical assistance session with these groups for this purpose?

Answer. HCFA would be glad to provide technical assistance to the protection and Advocacy agencies in States. We will coordinate this effort with the Administration on Developmental Disabilities.

FEDERAL MONITORING OF CERTIFIED PSYCHIATRIC HOSPITALS

Dr. Davis, in our hearing with Secretary Heckler a few weeks ago, I raised the issue of the Federal role in monitoring psychiatric hospitals certified for participation in the Medicare and Medicaid programs. In order to become certified, facilities must demonstrate first, that they comply with health and safety standards, and second, that they are providing active treatment. The Federal Government has the authority to ensure these requirements are being met through monitoring surveys.

Specifically, with regard to active treatment, in 264 hospitals, consultants employed by the Federal Government conduct surveys to measure compliance with active treatment requirements, while in 189 certified hospitals, the States conduct these surveys. In other words, there is no Federal presence in 189 hospitals, save for the monitoring surveys HCFA may conduct. However, last year only 9 of these 189 facilities were inspected, or about 5 percent.

Question. Do you believe this is an adequate percentage, in view of the high levels of inactivity and apparent lack of therapeutic programming on the wards of many of these facilities?

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Answer. HCFA believes it is. HCFA consultants survey directly 264 psychiatric hospitals for the two special psychiatric conditions of participation. This is almost 60 percent of the total. We also conduct a 5 percent sample of the remaining 189 psychiatric hospitals that have their two special conditions reviewed by the States. In addition, regions have authority to shift additional staff effort to psychiatric hospital oversight if necessary.

This is a higher level of Federal involvement than for any other facility type. We must recognize the fact that problems will occur in psychiatric hospitals--even in excellent facilities. However, we believe this level of Federal involvement is sufficient to carry out our responsibilities.

Question. Is it appropriate to rely on the State's judgment in the majority of facilities that won't receive a monitoring survey, when there is a strong financial disincentive for States to decertify the facilities they operate?

Answer. Section 1864(a) of the Social Security Act provides, "The Secretary shall make an agreement with any State health agency which is able and willing to do so," to make determinations whether a facility meets the conditions specified for participation as a provider under the Medicare program. However, the HCFA Regional Offices review the certification survey packages before exercising final determinations regarding certification decisions. We provide periodic survey and certification education workshops to ensure appropriate applications of Federal requirements. Federal direct surveys are also conducted in all cases where questionable findings occur. It is important to note that HCFA consultants survey almost 60 percent of all psychiatric hospitals to ensure compliance within the two special psychiatric conditions of participation. In addition, HCFA monitors 5 percent of the remaining psychiatric hospitals to check compliance status against the State agency decisions.

Question. Finally, since I was unable to obtain a response from Secretary Heckler on the procedure for referring cases of abuse and neglect in psychiatric hospitals to the Justice Department, could you respond to that question? Also, how often has this occurred?

Answer. First, let me point out that although both the Department of Health and Human Services and the Department of Justice are concerned about the individuals residing in these institutions, our authorities are separate and distinct under the law. Our authorities, of course, primarily relate to compliance with conditions and standards facilities must meet to participate in Medicare and Medicaid. Within this context, there are two primary ways these Departments coordinate their activities.

When the Department of Justice investigates a facility, it routinely advises us both when it is about to undertake the investigation and before it issues the final report. Similarly, we have established a mechanism by which we provide the Department of Justice with notice of the termination of a facility. We do not

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routinely inform the Department of Justice of our routine surveys because the magnitude of this information would make any practical use virtually impossible.

I cannot provide explicit information on numbers of facilities because we do not maintain detailed records of the information. I can, however, reassure you that there is contact between our General Counsel's office and officials at the Department of Justice whereby information about findings for our Medicare/Medicaid facilities is shared.

PROPOSED EXTENSION OF PHYSICIANS' FEE FREEZE

The Administration's Budget proposes to extend the current Medicare physicians' fee freeze for participating physicians for an additional year, resulting in an estimated savings of $500 million in FY 1986.

Question. Do you believe that the extension of the freeze would remove the incentives offered by the Deficit Reduction Act for doctors who became participating physicians last October ?

Answer. The participating physician program enacted as part of the Deficit Reduction Act contained incentives for physicians to sign participation agreements. These include exemption from the freeze on the physicians' actual charges, publication of names of participating physicians in a directory, dissemination of names of participating physicians to beneficiaries via toll-free telephone lines at the Medicare carriers, decals and other indications of participation status and direct lines at the carriers for the electronic receipt of claims. These incentives to participate will be continued. The Administration's proposal to extend the freeze delays the timing of when participating physicians will have their fee screens updated.

In this time of fiscal crisis and enormous budget deficits, we must ask all sectors of the economy to do their part toward reducing the Federal deficit. Close to three-quarters of income to the Part B trust fund, which covers physicians' services, come from general revenues. Continued increases in general revenue consumption for Part B exacerbate the Federal deficit. Physicians' services are the second largest component of Medicare accounting for 24 percent in FY 1986. Extension of the freeze on physicians is appropriate as part of an across-the-board freeze on spending for Federal programs and for other reasons. Even with the provisions of the Deficit Reduction Act, Medicare spending for physicians' services is expected to increase by 12 percent between FY 1985 and FY 1986, making it one of the fastest growing activities in the Federal budget. Moreover, all physicians were largely unaffected by expenditure reductions in OBRA, TEFRA and the 1983 Social Security Amendments. Finally, only 27 percent of the three-year savings from the Deficit Reduction Act fell upon physicians.

Question. What percentage of physicians are "participating physicians" and what percentage of total Medicare physicians' payments do these doctors account for?

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Answer. The chart below summarizes the number of participants in one or more practice setting.

	Number Participating	Total Billing Medicare	Percent
Physicians	118,426	396,840	29.8
Limited License Practitioners	19,751	58,125	34.0
Suppliers	17,822	75,014	23.8

The latest data we have available indicates that 36.6 percent of all covered physician charges are associated with participating physicians. This is based on a report of 29 carriers out of a total of 50.

STATUS OF THE MEDICARE HOSPITAL INSURANCE TRUST FUND

Recent estimates by the Department and CBO indicate that the Hospital Insurance (HI) Trust Fund will likely not be exhausted before 1994. Although the imminent depletion of the trust fund has been avoided, long-term estimates show that the trust fund deficits will grow steadily worse over the next 25 years.

Question. What policy options are you considering to eliminate the long-term deficits of the HI Trust Fund?

Answer. Long-term deficits in the HI Trust Fund are an important reason for the proposals in the President's FY 1986 budget to be enacted. By dealing with the health care financing issues now, long-term deficits may be made more manageable. We are continuing to work on various competitive solutions, such as vouchers and capitation, which could bring more cost-efficiency to Medicare and the delivery system. These have the potential to moderate health care costs and Medicare outlays. The April 1 Trustees report now indicates the Trust Fund will be solvent through 1998.

DIAGNOSIS RELATED GROUPS (DRGs) AND PAYMENT FREEZE

Nationally-based payment rates to hospitals for diagnosis related groups are currently being phased in over a 3-year transition period. As a result, a given hospital's payment rate is based upon an evolving blend of that hospital's historical costs, its regional rate, and the national rate.

Question. Isn't a freeze on payments to hospitals participating in the Medicare prospective payment system without a simultaneous freeze in the pace of the transition to a nationally-based system likely to create inequities among these hospitals?

Answer. No. In constructing a prospective payment system, we anticipated that the transition from hospital-specific

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reimbursement to a nationally-based system would necessarily encourage changes in hospitals' production behaviors. Consequently, hospitals with cost experience closer to the national average would experience less dislocation from the transition to national rates than those with higher costs; more efficient providers would be able to retain the difference between their costs and the payments under PPS. To halt the phase-in to a national rate would penalize those hospitals which are achieving the greatest efficiency. (Of course, we will continue to maintain special payment approaches for hospitals with unique costs, such as sole community providers.)

PROPOSED FREEZE IN MEDICARE PAYMENTS TO HOSPITALS

Your FY 1986 budget proposes a freeze in Medicare reimbursement rates to hospitals at their FY 1985 levels, for an estimated savings of $1.8 billion next year.

Question. What impact would the payment freeze have on Medicare beneficiaries in terms of access to services and quality of care?

Answer. We do not anticipate any limitations on access to services or lessening of quality of care. Recent reports indicate that efficient hospitals will be able to operate under the freeze without suffering losses. Therefore, there should be no increased reluctance to accept Medicare patients.

Our Peer Review Organization (PRO) program is actively monitoring care provided in hospitals to assure that appropriate services are being provided to Medicare beneficiaries. This includes review of the range of services received by patients and other activities designed to assure that patients are not discharged prematurely. As the PRO program completes its implementation phase, we anticipate that such continuing reviews will assure maintenance of high quality care for our program beneficiaries and will have a positive effect on quality of care.

Question. How will you monitor the impact of the freeze?

Answer. HCFA already has in place an extensive PPS monitoring system. Data concerning admissions, length of stay, type of diagnosis and discharge destination are routinely collected from all hospitals. During the freeze, these data can be compared with earlier PPS experience to identify any changes in patterns of care. Similarly, data concerning amounts of payments made, including outlier payments, are also collected regularly and can be compared to an earlier period. Peer Review Organizations (PROs) will continue to monitor quality of care to assure that patients received appropriate services in the appropriate settings.

Question. How would your freeze proposal affect the financial viability of the nation's hospitals?

Answer. We do not anticipate any significant adverse impact on the financial viability of efficiently operated

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hospitals. Several recent trends in the delivery of hospital services should facilitate their ability to live within the frozen rates. Length of stay has fallen dramatically since the advent of the prospective payment system (PPS). In FY 1984, length of stay for all short stay hospitals decreased by a full day. Preliminary data from PPS hospitals indicated an even greater reduction in length of stay. This will lead to reduced use of resources to provide room, board, and routine nursing services.

Productivity in the economy as a whole increased 3 percent in each of the last two years. With the incentives for economy built into PPS, it can be assumed that hospital productivity would increase at a rate at least as high as the economy in general. Finally, recent economic data indicate that the actual rate of increase in the cost of goods and services purchased by hospitals is not as high as had been projected when the rates were established.

Question. What alterations in services provided by hospitals do you believe will occur as a result of the freeze?

Answer. Since there is substantial evidence that hospitals will not have substantial financial difficulties as a result of the freeze, we do not foresee significant changes in the types and amounts of services provided by hospitals. To the extent that hospitals might begin to place emphasis on these services which they can provide most effectively, patient care may be enhanced. Studies have shown that, the more often a specialized procedure is performed, the more likely the final outcome will be favorable. Similarly, patients may be more comfortable if duplicative or unnecessary tests are reduced. Our Peer Review Organizations are carefully monitoring patterns of care, not only to reduce overutilization, but to identify and correct situations where insufficient or inappropriate services are being provided, should such situations arise.

GAO STUDY OF PROSPECTIVE PAYMENT SYSTEM

Dr. Davis, a preliminary GAO report indicates that the Medicare Prospective Payment System may be forcing patients out of the hospital too soon and in poorer health than before the system was instituted. At the same time, your FY 1986 budget proposes a freeze on hospital reimbursement rates at their FY 1985 level.

Question. What is your response to the GAO report, and wouldn't the proposed freeze risk eroding the quality of care provided to Medicare beneficiaries by increasing the incentive to discharge patients earlier?

Answer. We have no evidence that there is a significant pattern of problems with premature discharges under PPS.

HCFA requires Peer Review Organizations to report all cases of hospital readmissions that, while medically necessary, appear to reflect premature discharge from a previous hospital stay. HCFA is aware of several hundred such alleged cases, nationwide. These cases represent an extremely small fraction of Medicare discharges.

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In addition, we are developing new policies designed to financially disadvantage hospitals that seek to discharge Medicare patients too soon.

RESTRUCTURING OF HOME HEALTH BENEFITS

The Administration's budget request envisions a $70 million savings through a revision in the methodology for calculating limits on reimbursement for medicare home health services.

Question. What are the elements of this proposal?

Answer. We are currently considering a number of refinements to the HHA limits methodology. The data now available is of sufficient accuracy to allow us to apply the limits by type of service, as the Congress recommended in the Conference Committee Report accompanying the Omnibus Budget Reconciliation Act of 1981. In addition, we are considering other improvements such as refinements to the methodology used to identify and exclude aberrantly high and low per visit costs from the data used to calculate the limits. The refined system will be in place July 1, 1985.

Question. How have average costs per visit changed over the past five years?

Answer. The following chart presents the average per visit costs of a sample of urban freestanding HHAs participating in the Medicare program. These sample data have been used to establish HHA cost limits in each of the years indicated.

Home Health Agency
Selected Average Per Visit Costs
Calendar Years 1980 - 1985

Type of Visit	1980	1981	1982	1983	1984*	1985
Urban Freestanding HHAs						
Skilled Nursing	$25.71	$35.65	$38.78	$41.97	$42.98	$44.91
Physical Therapy	$26.09	$35.74	$38.17	$41.31	$42.05	$43.11
Home Health Aide	$19.59	$27.13	$29.95	$32.42	$28.10	$29.00

* Initial year of data based on a single method of cost reporting implemented October 1, 1980. This uniform method has significantly improved accuracy of cost by type of service (e.g., skilled nursing, aide)

NOTE: 1984 and 1985 based on market basket inflation factors.

Question. How many Home Health Agencies (HHAs) are currently "bumping" the existing limits, and how many more do you expect to reach the limits as a result of your proposal?

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Answer. We estimate that 26 percent, or 1,350 of the approximately 5,300 participating HHAs will have costs in excess of the present aggregate limits. Were the present limits applied by type of service, the number of agencies with cost per visit for one or more services in excess of the limits would probably increase. However, we anticipate that, with the incentive given them by per service application of the limits, most of the affected agencies will initiate improved management, recordkeeping, and cost reporting techniques. With these improvements being implemented during the first year, agencies are subject to limits by type of service. We anticipate that the actual end of year increase in affected agencies would not exceed 8 to 10 percent.

The other refinements to the limits methodology, discussed above, may also increase the number of agencies with costs in excess of the limits. The impact of each change will be discussed once final decisions have been made on all of the refinements under consideration.

Question. Won't this change have the effect of reducing the availability of these services to individual beneficiaries?

Answer. While we expect an increased number of HHAs to exceed the proposed limits, we do not believe there will be a significant impact on the availability of services. Since providers have the capability to control costs and modify behavior to avoid disallowances of cost, we expect these limits to eliminate inefficiency and promote cost conscious behavior in many agencies.

Moreover, the rapid growth of new HHAs since 1979 has greatly increased the availability of services to Medicare beneficiaries. Between 1979 and 1984, the number of participating agencies increased from 2,500 to over 5,000. The average annual rate of growth of participating HHAs between 1981 and 1984 (14 percent) was twice that experienced between 1979 and 1981 (7 percent). In addition, more agencies are now providing a wider range of specialized services (i.e., therapies, medical social service). For these reasons, we believe the change in limits will encourage improved management and more accurate cost reporting without adversely affecting beneficiary access to home care services.

MEDICAID "CAP" PROPOSAL

Along with your proposal to cap Medicaid expenditures, a "Hardship Fund" of $300 million would be available in FY 1986 only for States that experience extraordinary costs above their limit.

Question. How did you arrive at this $300 million for the hardship fund?

Answer. The $300 million level was determined to be the appropriate level because it was sufficiently large to provide relief to those States having difficulties adjusting to the new Federal financing limits, while not so large as to provide the wrong incentives to States in their efforts to control their rates of increase in Medicaid spending. It was determined that this

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amount would cover "excessive" cost increases above and beyond the level at which States could be expected to achieve savings through implementation of cost control and efficiency measures.

Question. What criteria would States have to meet in order to tap this fund?

Answer. The precise details have not yet been finalized. In general, the basic concept is to provide funds to States who are significantly above their Federal limit despite sincere efforts to control costs within the constraints of their existing programs.

MEDICAID "CAP" PROPOSAL

Your budget proposes to limit Federal Medicaid expenditures for medical assistance payments to $22.2 billion in FY 1986. This limit represents a reduction of approximately $1.3 billion below the current spending projections made by the Department.

Question. Do you feel that some States could be penalized unfairly because all future Federal payments would be linked to payments in FY 1984?

Answer. We gave the allocation procedures for the Medicaid cap considerable thought before we selected the option of using the latest actual expenditure data for allocating funds in FY 1986. This choice avoids the substantial uncertainties involved in attempting to estimate future demand and the numerous variables that may affect it. To account for factors that might arguably be important in such projections--such as tax bases and the share of indigent population--would require development of consistent estimates of the effects of each of these factors on a State-by-State basis. In many cases, the data needed to develop such estimates are not reliable or not even collected at a State level. Therefore, using data that reflects the most recent actual experience of the States is preferable. The $300 million hardship fund would be available to States with costs significantly above their grant despite vigorous cost-control efforts. We realize, however, that after 1986, there may be a need to reapportion funds based on changing State circumstances, and we will be examining various criteria which might be used in making reapportionments.

Question. How would States with worsening economic conditions be able to adjust to the proposed ceiling?

Answer. This proposal is being introduced at a time that the Federal government is facing continued deficits of an unacceptable magnitude. The relative financial health of the States indicates that it is time for them to increase their share in paying for the health care of their citizens. A State facing worsening conditions will have to make the same decisions it has always had to make: to shift monies from different programs, to reduce over-all spending, and/or to increase revenues. Further, we believe that under a limited Medicaid program, States would have the incentive to organize cost-effective systems of care and explore innovative ways of financing and delivery services. For

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example, GAO reports that Medicaid pays for more than $500 million annually in uncollected third party payments, and HCFA estimates that eligibility errors result in erroneous expenditures in excess of $400 million. Aggressive action in these areas should assist States in achieving savings and adjust to the proposed ceilings.

Question. Do States which have recently implemented major program changes have the ability to institute significant additional program efficiencies without affecting the quality and accessibility of services?

Answer. We expect that the "cap" on Medicaid will be implemented by the States in a variety of ways depending on choices that the States make. We intend to remove a number of requirements that now restrict the States' flexibility to tailor their programs to their individual needs. The resulting increase in flexibility should permit the States greater opportunity for improving the cost-effectiveness of their programs. It is our opinion that the FY 1986 funding level, which is approximately 5 percent less than the current law estimates, will not require the States to make significant reductions to those beneficiaries who are currently eligible for Medicaid.

The States have demonstrated great creativity adapting to the reductions in the Federal Medicaid payments between 1982 and 1984. The FY 1986 budget request would give the States strong incentives to continue efforts to manage their programs cost-effectively. For example, we estimate that the current Medicaid eligibility error rate of 2.7 percent represents over $400 million a year in erroneous expenditures and that uncollected payments from third-parties total $500 million a year. More determined efforts by States in these areas, for instance, could afford substantial savings.

MEDICARE HOME HEALTH COPAYMENTS

Your Medicare budget proposes to establish a copayment equal to one percent of the inpatient hospital deductible on all home health visits after the 20th visit in a calendar year. You estimate that the copayment amount would be $4.80 in FY 1986, and would result in savings of up to $65 million next year.

Question. How many persons would be affected by the proposed copayment on home health visits?

Answer. In 1982 about 450,000 Medicare beneficiaries received more than 20 home health visits. We estimate that roughly 500,000 beneficiaries would receive more than 20 visits a year and thus would be affected by the proposed home health copayment. If this proposal were in effect in FY 1985, beneficiaries who use home health services would, on average, face copayments of $20.00 per year.

Question. What do you anticipate the impact of this proposal on utilization of home health services?

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Answer. This proposal is intended to impose a modest copayment on home health services to give beneficiaries and their physicians the same financial incentive that exists for hospital and SNF benefits to consider whether services are needed. This modest copayment should bring home health utilization in alignment with the rest of Part A. The amount was set at a modest level so that persons in need of services would continue to receive such services.

Question. Is it appropriate to discourage the utilization of home health services at the same time patients may need such services because of earlier discharges from hospitals?

Answer. Persons who need no more than 20 visits after a hospital stay would not be affected by the copayment. The modest level of the copayment should serve only to discourage unnecessary utilization. Beneficiaries who need services should not be discouraged by a modest copayment.

RESEARCH AND DEMONSTRATIONS

Your FY 1986 research budget is proposed for a one-third reduction, down from $33 million in FY 1985 to $22 million. At the same time, there are several Congressionally mandated reports on Medicare policy and implementation issues that are already overdue, and approximately 17 more which are due over the next three years.

Question. What impact will this reduction have on the adequacy and timeliness of the reports due to Congress on these issues?

Answer. We have carefully targeted our resources to assure continued funding of research addressing the priorities that have been expressed by both Congress and the Administration. The proposed budget also permits us to target additional resources on those new initiatives of highest priority to the Administration and the Congress. We will continue to be responsive to the concerns of Congress in our agenda-setting process.

SKILLED NURSING FACILITIES

Your budget proposes to freeze Medicare reimbursement rates to Skilled Nursing Facilities (SNFs) at the prior years' level for accounting periods beginning July 1, 1985.

Question. How many skilled nursing facilities have reached the payment limits? How many more facilities do you expect to bump the limits as a result of your proposal?

Answer. As of July 1, 1984, the DEFRA 50 percent add-on to the freestanding SNF limits for hospital-based Medicare SNFs went into effect. HCFA data indicate that under these limits, 48 percent of urban hospital-based facilities and 36 percent of rural hospital-based facilities have costs exceeding these limits.

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Twenty-three percent of freestanding urban facilities and 23 percent of freestanding rural facilities have costs exceeding the limits applicable to freestanding SNFs. We have no estimates available as to how many facilities would reach the limits as a result of the SNF limits freeze proposal. It is important to note that since facilities would know about the limits freeze in advance, they would have the opportunity to institute cost containment measures to mitigate adverse impacts.

Question. Is it true that savings resulting from institutions exceeding limits for SNFs come from facilities which accept large numbers of Medicare patients?

Answer. Hospital-based facilities, which are also the facilities with higher costs and those currently most likely to exceed the SNF cost limits, do tend to serve greater proportions of Medicare patients. Thus, the 10 percent of Medicare SNF beds that are in hospital-based facilities provide 20 percent of Medicare SNF patient days. Note, however, that 80 percent of Medicare patient days are being provided in beds in freestanding facilities which, on average, have lower costs.

Question. If so, wouldn't this proposal create disincentives for facilities to accept Medicare beneficiaries?

Answer. Analyses of cost variations among Medicare SNFs indicate that only some of the costs in higher cost facilities can be explained by such case-mix variables as higher proportions of Medicare patients. DEFRA sought to recognize only those higher costs attributable to case-mix differences in hospital-based facilities by allowing these facilities a 50 percent add-on to the freestanding facility cost limits. To the extent that other factors--such as higher wage rates, more staff, and lower efficiency--account for the remainder of the differences in costs between hospital-based and freestanding facilities, the high cost facilities could institute cost containment measures to control the effects of these factors without necessarily rejecting Medicare patients.

MEDICARE VOUCHERS

The Administration proposes to establish a voluntary Medicare voucher program under which beneficiaries could elect coverage under a private health benefits plan rather than Medicare. Under this approach, a beneficiary choosing to do so would "opt out" of the Medicare program and receive a voucher toward the purchase of private insurance or a health maintenance organization plan.

Question. If the HMO experience is a model for your voucher plan, what evidence do you have that the voucher system would be more efficient than the HMO system?

Answer. The voucher proposal expands on the HMO system now in place. It is intended to give beneficiaries a broader range of

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options by permitting a wider range of health insurers to contract with Medicare to cover a benefit package at least equivalent to Medicare.

Under this proposal, the Medicare program would give the plan a payment related to Medicare's average payment for a beneficiary, adjusted by actuarial categories such as age. In return, the plan would assume the risk of covering the beneficiary's services. While plans would have some flexibility in adjusting the structure of Medicare benefits, they would have to offer a package at least equal in value to Medicare. Beneficiaries would be free to return to Medicare should they so choose.

Plans would have to meet certain requirements, for example, standards regarding their financial stability to assure that they are viable business operations and that they ensure continued access to quality services.

There would be greater program efficiencies because more plans would be able to offer an integrated package of Medicare coverage combined with "Medigap" benefits, as HMOs can now do. These insurers would have incentives to be more efficient and to develop reasonable utilization controls because they would be at risk for both Medicare and Medigap benefits. At the national level, the health care sector would benefit from the increased competition and efficiency among plans that would be generated by opening up the Medicare market to a wider array of health care insurers.

Question. Has the private insurance industry given you any indication that they will be able to provide the elderly with insurance benefits equivalent to those offered under Medicare at a rate which will result in savings to the Federal Government?

Answer. Since the voucher bill was introduced in 1983 we have had feedback from several sources, some indicating interest in the concept. Other insurers have indicated that they might not be interested in being at risk for covering a Medicare-equivalent package of benefits. However, these plans could change their position if they see their competitors entering into agreements with HCFA. The proposal provides that the Federal Government will pay 95 percent of the amount it otherwise would have, resulting in federal savings.

MEDICARE AND PREPAID HEALTH PLANS

Premiums paid by Medicare to prepaid health plans participating in Medicare are equal to 95 percent of the Adjusted Average Per Capita Cost (AAPCC). The AAPCC is an estimate of the cost Medicare would have paid providers in the Fee-For-Service System to care for the prepaid plans' Medicare beneficiaries.

Question. How may prepaid health plans have expressed an interest in participating in Medicare? How many contracts have been signed with these plans?

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Answer. Ninety-four organizations have applied for contracts under the new prepaid health plan provisions. Of this number 27 (formerly demonstration contracts) have signed contracts and are operational.

Question. How many Medicare beneficiaries do you expect to enroll in these prepaid plans in the next year? What share of all Medicare beneficiaries do you expect will ultimately enroll in these plans?

Answer. We expect enrollment to increase by 100,000 to 200,000 in the next year as new prepaid health plan contracts are implemented. Over the long run, we believe enrollment by Medicare beneficiaries in HMOs will match the proportion of the general population in HMOs. This presently stands at 6 percent.

Question. Do you expect this system to result in additional costs or achieve net savings to Medicare over the long term?

Answer. We expect the system to achieve net savings to Medicare in the long term. Our data shows that program savings for Medicare enrollees for 1984 were $20.9 million and estimated savings for 1985 will exceed $34 million. We expect continued growth in savings as the number of contractors and enrollees increases.

MEDICARE PAYMENT FOR MEDICAL EDUCATION COSTS

Your FY 1986 budget proposes to freeze Medicare payments for direct medical education costs and to halve payments for indirect medical education costs.

Question. How would these proposals affect the financial stability of teaching hospitals?

Answer. Since the beginning of Medicare, we have paid for direct medical education using an open-ended cost-based methodology. These costs have increased at a rate above the overall rate of inflation. We do not believe that the entire increase is necessary for the efficient delivery of patient care. We do believe that the proposed limitation will result in appropriate payments for these direct costs.

While we recognize that this change will temporarily have an adverse impact on affected hospitals, we believe that this policy offers hospitals an opportunity to be more efficient and flexible in their approach to managing their education programs. For example, some hospitals may choose to specialize in certain residency programs.

In regard to indirect medical education, the proposal is to return to the initial factor used by HCFA to estimate these costs. We will still pay for these costs but we will not pay based on an arbitrary doubling of the factor. In addition, since the indirect

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teaching adjustment is applied to only one-half of the hospital's DRG payment in FY 1985, the impact on teaching hospitals is reduced on average by 25% from 5.79% of the total DRG payment in FY 1985 to 4.35% of the total DRG payment in FY 1986.

Question. What effect would these proposals have on the size and scope of their teaching programs?

Answer. We do not anticipate that the changes to indirect medical education will affect the size and scope of teaching programs since these payments do not directly support medical education. Our proposal to limit direct medical education could lead to changes in the number of programs, their size or their specialty make-up, however, we are unable to predict what specific actions affected hospitals will take in response to the proposed payment limitation.

Question. How would any negative impacts resulting from these proposals, compounded by a freeze in prospective payments rates, be addressed?

Answer. Any time that reimbursement is reduced, an adjustment period follows. However, we do not anticipate any permanent adverse impact from our proposals. Once the changes are implemented, we will continue to monitor the status of teaching hospitals and consider any further actions that may be warranted.

PROPOSED MEDICARE PART B PREMIUM INCREASE

Your budget proposes to gradually increase the Medicare Part B premium over a 5-year period beginning in FY 1986. This would increase the premium next year from $16.10 under current law to $16.80.

Question. What would be the effect of this premium increase on beneficiaries who are already at or near the poverty line?

Answer. State Medicaid programs currently pay the Medicare Part B premium for 2.8 million cash assistance recipients. These individuals will not be affected by the proposal since the State will pick up the increased cost.

In addition, the proposal contains a hold-harmless provision to protect beneficiaries with low Social Security payments. Under this provision, beneficiaries who have their Part B premium deducted from their monthly Social Security benefits check will not see a reduction in their Social Security check as a result of the proposed change. That is, if the dollar amount of the premium increase is greater than the dollar amount of their Social Security cost of living adjustment, the beneficiary's premium increase is reduced to equal the Social Security Cost of Living Adjustment.

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PROPOSAL TO INDEX MEDICARE DEDUCTIBLE FOR MEDICARE PART B

Current law requires enrollees in the Part B (doctor bill) portion of Medicare to pay a $75 annual deductible. Your proposal would index that deductible to the Medicare Economic Index beginning in 1987, for an estimated savings of $75 million that year.

Question. What effect would this change have on Medicare Part B beneficiaries?

Answer. The 1981 Reconciliation Act increased the Part B deductible 25 percent from $60 to $75. Prior to this amendment, the deductible had remained at $60 since 1973 despite a more than 500 percent increase in total program benefits (more than 300 percent per aged enrollee) between 1973 and 1982. Current law does not provide for future increases in the deductible despite a projected 121 percent increase in Part B reimbursements between 1981 and 1985. As a result, the initial beneficiary liability for medical services will decrease in real terms and these costs will be shifted to the Federal government.

The Administration's proposal would raise the Part B deductible by $3 on January 1, 1987 from $75 to $78. Under current assumptions, the deductible would increase to $81 in 1988, $85 in 1989 and $89 in 1990, relatively modest amounts which beneficiaries can bear. Beneficiaries most in need would be protected since increased deductible amounts would be picked up by State Medicaid programs. Moreover, many Medigap policies cover Part B deductible expenses for beneficiaries.

PROPOSED DELAY IN INITIAL ELIGIBILITY DATE FOR MEDICARE ENTITLEMENT

Current law states that eligibility for Medicare begins at the beginning of the month in which an individual turns 65 years old. The Administration's budget proposal would delay eligibility until the first day of the month following the individual's 65th birthday, for an estimated savings of $225 million in FY 1986. As you know, Congress considered, and rejected, this proposal last year.

Question. What assurance do you have that employer-based health insurance plans would extend private coverage for an additional month if the program's initial eligibility date were delayed?

Answer. Many private plans now cover periods until Medicare begins. Further, if Medicare eligibility were extended to the first full month following the 65th birthday it would create a demand for private coverage for that period. It is reasonable to expect that private insurers would seek to meet the demand, especially since it would be an administratively simpler matter for them to extend existing coverage to the beginning of a month for all persons turning 65 in the previous month.

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Question. Do you have an estimate of the number of persons who lack employer-based or private health insurance at age 64 and would therefore be without coverage for an additional month?

Answer. About 16 percent of persons aged 64 have no employer-based or private health insurance coverage. Half of these people have public coverage, i.e., Medicaid, CHAMPUS, or Medicare (entitled because of disability). The remainder have no coverage. About two million people will become newly entitled to Medicare at age 65 in 1986. About eight percent of this group, or roughly 160,000 persons, would be without coverage for an additional month if this proposal were enacted.

PEER REVIEW ORGANIZATIONS (PROs)

Hospitals receiving payment under the Medicare prospective payment system were required to enter into agreements with a Peer Review Organization by November 15, 1984, which would conduct reviews of: (1) the validity of the diagnostic information provided by the hospitals; (2) the completeness, adequacy, and quality of care provided; and (3) the appropriateness of admissions and discharges.

Question. What are your criteria and procedures for monitoring and evaluating the performance of individual PROs?

Answer. In order to effectively monitor and evaluate the performance of PROs, several steps will be taken:

1. Quarterly progress reports on the status of utilization objectives will be required.

2. Routine visits by contractors with medical expertise will be made to monitor the progress of PROs' quality objectives.

3. On-site visits by project officers to validate reports, identify problems, and to discuss probable solutions with the PRO.

4. The accuracy of medical determinations made in the course of admissions review and DRG validations will be verified by an independent, nationally recognized organization of physicians, nurses and records administrators (Super PRO contract).

The activities listed above will take place within the first 15 months of a PRO contract. Problems identified will require the submission of corrective action plans which will be monitored by the project officer and/or medical contractor group. These two entities will also be available to provide technical assistance to PROs.

Further, a comprehensive evaluation of the PROs' overall performance will be conducted during the 18th month of the contract. Minimum criteria sets will be established for cost effectiveness, quality, coordination with Fiscal Intermediaries and investigative agencies, reporting requirements and private review.

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Failure by a PRO to meet any of the minimum standards creates a basis for termination, nonrenewal, or modifications of the PRO's contract.

Question. What have been the major problem areas identified by PROs in the course of conducting hospital reviews?

Answer. The major problem area in implementing and conducting hospital review has been the lack of acceptable Part B bill tapes, including delayed receipt of claims, high error rates, problems with new system as well as the data exchange between PROs and Fiscal Intermediaries. Edits have been put into place to resolve many of these problems. Another problem area has been the requirement that physician and provider contact be made prior to the issuance of denial. A directive was issued in early February to stress this requirement and to make available to the PRO additional time to complete review, if needed to facilitate physician/provider contact. Several PROs experienced problems with data processors and evaluations and terminated their services, replacing them or making a decision to perform the services themselves.

Backlogs of reviews that needed to be completed before performing correct review was a major problem to a number of PROs until they were able to catch up. Several PROs had problems hiring personnel with needed expertise to perform all the review requirements.

Question. What recourse do patients and their physicians have in the case of an individual who has received an initial PRO denial determination during preadmission review?

Answer. If a Medicare beneficiary is refused admission by a PRO to a hospital, he or she must be notified in writing of the reasons for the denial. The beneficiary may request that the PRO reconsider its findings by submitting such a request within 60 days of the denial to 1) the PRO; 2) any Social Security Office; or 3) any Railroad Retirement Board Office. If the PRO upholds its original determination and the amount in controversy is over $200, the beneficiary may obtain a hearing by an Administrative Law Judge of the Social Security Administration. If the amount in controversy is over $2,000 the beneficiary may obtain judicial review of the case. If a beneficiary suspects that he or she was discharged too early, or transferred inappropriately or in some other way did not receive quality care, he or she may contact the PRO or HCFA or the Office of the Inspector General and request an investigation.

END-STAGE RENAL DISEASE NETWORK COORDINATING COUNCILS

Your budget once again proposes elimination of the ESRD Network Coordinating councils, which were funded at $4,837,000 in FY 1985.

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Question. How will the new responsibilities of the Councils added by the Deficit Reduction Act be carried out if the Councils are eliminated?

Answer. The Congress has directed the Administration to address the following concerns.

1. Consider consolidating existing network areas.

   The Administration has determined that the activities which the Councils perform can be assumed by other programs HCFA manages. With regard to network areas, HCFA is developing a plan to reduce the number of network areas from the current 32.

2. Strengthen the networks' data collection capability.

   Collection of program data currently performed by the Councils will be accomplished by Medicare fiscal intermediaries, HCFA regional offices, or independent contractors. HCFA will ensure that these entities will have sound data collection capability.

3. Examine the composition of network organizations to see if facility representation could be reduced and representation of the beneficiary's interest could be increased.

   HCFA will require a Patient Advisory Committee in all network areas which will provide increased representation from the beneficiaries' perspective.

Question. How has your establishment of a composite reimbursement rate for ESRD facilities encouraged home-based dialysis?

Answer. The ESRD composite rate is paid to a facility for its Method I patients who dialyze at home. Because the composite rate payment exceeds the cost incurred by a facility for these patients, it is anticipated that the number of home-based dialysis patients will gradually increase. Since the introduction of the composite rate system on August 1, 1983, the percent of Method I home dialysis patients has increased from 17 to 19.2.

WAGE INDEX FOR PROSPECTIVE PAYMENT RATES

The wage index used to develop the FY 1984 and 1985 prospective payment system rates is based on data from the Bureau of Labor Statistics that does not distinguish between full-time and part-time workers. The wage index therefore understates wage levels in areas that rely more heavily on part-time workers, such as rural areas. We understand that HCFA is attempting to develop a revised wage index.

Question. What is that status of this effort?

Answer. I am pleased to report that on March 29, 1985, Secretary Heckler submitted to the Congress the wage index study

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required by the Deficit Reduction Act. The report contains two alternative wage indexes developed from a survey of hospitals subject to the PPS. The survey was especially designed to address the principal limitation of the present index, its inability to measure regional variation in hospital part-time employment. The report contains no recommendation with respect to which index should be adopted. Before an index is adopted, we want to have the benefit of comments from the Congress, the hospital industry, and other interested parties.

EXPIRATION OF MEDICARE HOSPICE BENEFIT

Dr. Davis, your budget assumes that the Medicare hospice benefit will expire at the end of FY 1986, as the law currently dictates.

Question. Why is the Department not proposing legislation to extend the benefit? Has it been shown to result in higher costs to the Medicare program?

Answer. When the hospice benefit was enacted in 1982, Congress directed that we study our experience under the benefit and provide a report by January 1, 1986. We are now in the process of collecting data and information to develop that report and believe it would be premature to make any legislative proposals until it is completed. We do not presently have cost data to determine the financial impact of the hospice benefit on the Medicare program. However, our actuaries have previously estimated that the hospice benefit will increase Medicare program costs.

Question. Do the preliminary results of the Medicare benefit indicate that the majority of hospice patients are cared for in home-based or hospital-based hospices?

Answer. Seventy-seven of the 171 hospices currently approved for Medicare participation are home health agency-based organizations. The remaining hospices fall into the following categories:

42 Hospital Based
9 Skilled Nursing Facility Based
43 Freestanding

Question. When can we expect to receive the HCFA evaluation of the hospice demonstration project, which was due in September 1983?

Answer. The final hospice report is currently being reviewed within the Department. We expect the Secretary to officially transmit the document to Congress by the summer of 1985. An interim hospice report was shared with the Congressional staff in April 1984.

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MEDICARE HOSPICE BENEFIT

Last year you indicated that HCFA projected that of the over 1,500 hospices nationwide, approximately 400-500 hospices would become certified for participation in the Medicare program. Yet only about 100 or so have actually become participants in Medicare.

Question. On what did you base your initial projections that approximately 400-500 hospices would become certified for participation in the Medicare program and why do you think more hospices have not chosen to become Medicare certified?

Answer. Prior to publication of final hospice regulations, HCFA canvassed 1500 potential hospices to determine their interest in the Medicare hospice benefit. Over the next several months, 500 responses were received from the hospices and most of them indicated that they intended to wait until the regulations were published in final before considering applying to the Medicare program. However, upon publication of the final hospice regulations a smaller than expected number of hospices actually applied for Medicare approval.

In a report issued by the Department of Health and Human Services' Inspector General, the major disincentives in the current regulations focused on cost and reimbursement factors. These include:

1. Reimbursement rates viewed as insufficient by hospices.
2. $6,500 reimbursement cap per patient.
3. Required care services plus new recordkeeping and reporting obligations would add appreciably to administrative overhead and operating costs.

Some hospices may view specific hospice "model" laid out in TEFRA as inconsistent with their goals and philosophies.

HCFA RESEARCH, DEMONSTRATION AND EVALUATION

You are proposing a 33 percent cut in the Health Care Financing Administration's budget for research, demonstration and evaluation (RD&E) activities, from $33 million in FY 1985 to $22 million in FY 1986. These RD&E efforts are directed toward developing and testing alternatives for administering the Medicare and Medicaid programs more cost effectively.

At the same time you are proposing this reduction, your budget justification acknowledges that "there is little likelihood that other organizations would carry out the necessary RD&E activities to help contain HCFA program costs."

Question. How do you justify a reduction of this magnitude in view of the serious financing problems facing the Medicare and Medicaid programs?

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Answer. In view of the overall need to do everything possible to reduce the deficit, we have carefully reviewed the needs of our RD&E activities for FY 1986. This level of funding will provide the resources to assure continued funding of research addressing the priorities that have been expressed by both Congress and the Administration. The proposed budget also permits us to target additional resources to those new initiatives of highest priority to the Administration. We will continue to be responsive to the concerns of Congress as we develop our research agenda.

Question. What specific projects will be foregone as a result of this reduction?

Answer. As in any research and demonstration program, there are always more worthy projects than available resources. However, we believe that the funding level of $22 million in FY 1986 will enable the Health Care Financing Administration (HCFA) to fund all current Congressionally-mandated studies, all priority continuations as well as high priority new starts. Much of HCFA's effort over the last several years has focused on the implementation of the Prospective Payment System and the Health Maintenance Organization Program, which are now in place. We will now be shifting our focus to more long-term reforms and refining the research agenda in FY 1986.

MEDICARE CONTRACTORS

I understand that HCFA has requested that HHS seek approval from OMB for release of the $20 million FY 1985 contingency fund for the Medicare contractors.

Question. What is the status of this request? Will you need the entire $20 million? If so, will even that amount be sufficient?

Answer. Possible use of HCFA's contingency fund is currently under review within the Department.

Question. Will you be using any of the contingency funds to cover claims processing?

Answer. Possible use of HCFA's contingency fund is currently under review within the Department.

Question. Do you anticipate a similar problem in FY 1986, since your budget request of $935 million is basically a straight line budget, while contractor workloads are expected to rise between 6-10%?

Answer. The FY 1986 Medicare contractor budget does take into account workload growth, inflation, and other demands on the contractors. The budget also takes into account economies and efficiencies which contractors, particularly high cost contractors, are expected to achieve.

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Question. Is it true that your request to OMB for Medicare contractors was $957 million in FY 1986?

Answer. Our submission to OMB for the Medicare contractors was $935 million. HCFA's request to the Office of the Secretary was $957 million.

Question. If your FY 1986 budget request proves to be inadequate, what would be the consequences to Medicare beneficiaries and contractors?

Answer. The funding level requested for FY 1986 for the Medicare contractors is sufficient. HCFA's goal is to increase the efficiency and productivity of the Medicare contractors while not reducing the quality of their operation.

The beneficiary and provider services portion of the FY 1986 Medicare contractors' budget has been increased by $13.3 million. This increase will assure that contractors maintain adequate communications with beneficiaries, and affords beneficiaries the opportunity for reconsiderations and fair hearings concerning adjudication of their claims.

"SUPER" PEER REVIEW ORGANIZATION CONTRACT

I understand that HCFA is planning to contract with an organization to review the work of the Peer Review Organizations (PROs), hopefully within the next few months.

Question. Since the PRO contracts are coming up for renewal during the summer of 1986, will awarding of this contract in late spring of 1985 allow sufficient time for review of the PRO's activities? If not, will you rely on the HCFA regional offices' evaluations of the PROs?

Answer. We expect to award a "Super-PRO" contract in June 1985. The first significant point in the PRO contracting process occurs at the 15th month of each contract, i.e., September 1985 for contracts effective July 1984; October 1985 for contracts effective August 1984, etc. The first set of contract deliverables for the Super-PRO contract have been scheduled to coincide with the 15th month of each PRO contract and we intend to use those reports as part of our overall assessment of PROs. However, it is not our intention for the Super-PRO contract to replace HCFA regional office evaluations but rather to supplement HCFA regional monitoring activities.

It should also be pointed out that the Super-PRO contract period extends beyond the existing PRO contract periods. This will enable us to monitor the second set of PRO contracts from the start of the contract period.

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ICF/MR AND DEVELOPMENTAL DISABILITY SPECIALIST POSITIONS

Question. From what survey activities will the 12 staff be directed, and how did you determine that these survey activities were of lower priority?

Answer. The 12 staff will be directed from monitoring those providers and suppliers that historically experience a small percentage of deficiency citations. These facilities include comprehensive outpatient rehabilitation facilities (CORFs), ambulatory surgical centers, portable x-ray units and rural health care units. HCFA has determined that these staff will have a greater impact on its monitoring responsibility by focusing on ICFs/MR.

Question. What will be done with the remainder of the $1.9 million that will now not be needed.

Answer. The majority of the remaining funds were used to pay the FY 1985 3.5 percent payraise.

RESCISSION

Question. Please provide for the record a breakout of the proposed FY 1985 rescission by category (i.e., travel, consultants, publications) and its effect on Program Management Projects. In particular, please include any research or demonstration projects that would be reduced or foregone if this rescission were to be enacted.

Answer. HCFA plans to reduce the Program Management Account in the following manner:

Category	2901 Savings Amount	515 Withholding Amount	Total
Travel	$ 163	$ -	$ 163
Transportation of Things	4	-	4
Printing	1,244	-	1,244
Public Affairs	63	-	63
Consultants	4,337	1,432	5,769
	$ 5,811	$ 1,432	$7,243

The rescission will result in:

Travel and Transportation

- A slight reduction in travel and transportation with no adverse impact.

Printing

- A reduced level of certain Medicare publications in addition to other types of Agency printing material.

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Public Affairs

o The cancellation of a contract to distribute Medicare pamphlets.

Consultants

o Spending reduced below the 1984 level. The proposed reduction would decrease consultant expenditures by 41% as follows:

+ A 45% decrease in PRISM funding which will extend, at the most, one year, the planned redesign of the HI/SMI systems and the Medicare Statistical Systems.
+ Reduction in several other miscellaneous contracts such as:
  - Emergency Preparedeness
  - Claims Processing - State Audits
  - State Agency Performance Evaluation System
+ Research Contracts ($1.3M Rescission, $1.0M Lapse).
  - Physician/Hospital DRG Demonstration
  - Hospice Evaluation

FEDERAL MONITORING OF PSYCHIATRIC HOSPITALS

Question. In the case of the 80 percent of certified psychiatric hospitals that are also accredited by the Joint Commission on Accreditation of Hospitals, is it true that you rely largely on State agencies to perform surveys validating JCAH standards are being met?

Answer. First, let us point out that hospitals accredited by the Joint Commission on Accreditation of Hospitals are deemed to meet only the general hospital conditions; they are not deemed to meet the special psychiatric requirements. Therefore, with regard to validations, accredited psychiatric hospitals are treated no differently from accredited general hospitals. That is, we rely primarily on the State agencies to verify that accredited hospitals do meet the Medicare general hospital conditions.

For the two special psychiatric conditions, in both accredited and unaccredited hospitals, we also rely heavily on the State agencies to certify compliance. However, most States (all but 12), instead of using their own surveyors, use HCFA psychiatric clinical consultants. (In over half of the psychiatric hospitals surveyed in FY 1984, HCFA psychiatric clinical consultants were used to evaluate compliance with the two special conditions). Those States that do not use our consultants are strongly encouraged to do so.

Question. When a complaint is made to HCFA of substandard conditions in these facilities, does your agency investigate or do you contact the States to have them follow up on complaints?

Answer. Generally the States perform complaint investigation surveys for us. For complaints against psychiatric facilities, HCFA consultants are frequently used, especially in those States where consultants perform the routine certification surveys. In almost all cases, if the complaint is serious enough (e.g., patient deaths) or requires an extremely high level of expertise to investigate (e.g., active treatment), HCFA consultants, are used in lieu of State Agency surveyors.

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CONGRESSIONALLY-MANDATED STUDIES

Question. Please provide for the record a list of all the Congressionally-mandated studies since 1980 and their due dates, as well as their current status.

Answer. Due to its length, this information is being sent to the subcommittee under separate cover.

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ANNUAL REPORTS

Report/Authority	Description	Due to Congress	Status
Annual Report on the Administration of Medicare (Sections 1875, 1881(g), and 1882(f)(2)(A)(B) of the Social Security Act	There is no legislatively stipulated date by which the Report on Administration of Medicare is to be submitted. However, the ESRD Annual Report and Medigap Biennial Report, which are included in the Annual Report are due by July 1. Therefore July 1 has been established as the due date for the entire report.	July 1[2] annually	1982, 1983, and 1984 report in preparation and are scheduled for release in October of 1985.
Medigap Section 1882(f)(2)(c) of the Social Security Act	Medigap criminal penalties		To be included in the 1983 Medicare Annual Report. Scheduled for release in October of 1985.
Peer Review Organizations Section 1161 of the Social Security Act	Requires the Secretary to submit a full and complete report on the administration, impact, and cost of the PRO program.	April 1[1] annually	FY 1984 report schedule for release in the near future.

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1/ Date established by legislation.

2/ HCFA projected completion date.

1282

Report/Authority	Description	Due to Congress	Status
Annual Report on the Validation of the Joint Commission on Accreditation of Hospitals (Section 1875(b) of the Social Security Act	Reports on the validation of the accreditation process of the JCAH.		Validation survey for FY 1981 and FY 1982 are considered too small to produce statistically significant findings and are therefore being combined into one report. which will be included In the 1982 Annual Medicare report which is awaiting signature. FY 1983 report also awaiting signature, but cannot be released until 1981 and 1982 reports are signed. FY 1984 draft report currently in review.
Annual Report of the Board of Trustees of the Federal Hospital Insurance Trust Fund (Sections 1817(b)) and 1841(b))	Report on the operation and status of the Trust Funds during the preceding fiscal year and on its expected operation and status during the current and next two fiscal years.	April 1 1/ annually	1983 report signed 4/5/84. 1984 report signed 3/28/85. Anticipate FY 1985 report will be released in July 1986.

1/ Date established by legislation.

2/ HCFA projected completion date.

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QUARTERLY REPORTS

Report/Authority	Description	Due to Congress	Status
1915 Waivers (Section 1915(e)(2))	The Secretary is required to report on the Medicare waivers granted to States under Section 1915 of the Social Security Act. Two reports are planned: one covering 1915(b) case management, freedom of choice, shared savings, and central broker waivers and one covering 1915(c) home and community based services waivers.	09/30/84[1/]	Anticipate release in August, 1985.

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1/ Date established by legislation.

2/ HCFA projected completion date.

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OTHER REPORTS

Report/Authority	Description	Due to Congress	Status
Impact of Prospective Payment Methodology (Sec. 603(a) of P.L. 98-21)	Requires the Secretary to study and report to the Congress on the impact of the prospective payment methodology during the previous year on classes of hospitals, beneficiaries, other payors for inpatient hospital services, other providers, and impact of computing averages by census division, rather than on a national basis. Report required annually beginning with 1984 and ending with 1987.	12/31/84[1]/ 04/01/85[2]/	Anticipate release in July, 1985.
Prospective Payment Studies (Sec. 603(a) of P.L. 98-21)	The 1985 annual report on prospective payment shall also include the results of studies on:	12/31/85[1]/	Studies 1 through 3 to be included as part of the 1985 Annual Report. Studies 4 and 5 are under discussion within HCFA.
	1. Urban - Rural - the feasibility and impact of eliminating or phasing	12/31/85[1]/	

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
	out separate urban and rural DRG prospective payment rates.		
	2. Uncovered Hospitals - develop a method under which hospitals not paid under the prospective payment system can be paid for inpatient hospital services on a prospective basis.	12/31/85[1/]	
	3. DRG Refinement - the appropriateness of the factors used to compensate hospitals for the additional expenses of outlier cases, and the application of severity of illness, intensity of care, or other modifications to the DRGs, and the advisability and feasibility of providing for such modifications.	12/31/85[1/]	

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
	4. All Payors - the feasibility and desirability of applying the prospective payment methodology to all payors for inpatient hospital services, including consideration of the extent of cost-shifting to non-Federal payors and the impact of such cost-shifting on health insurance costs and premiums borne by employers and employees.	12/31/85[1/]	Under discussion within HCFA.
	5. Impact of Admissions Volume Adjustment - the impact of the prospective payment system on hospital admissions and the feasibility of making a volume adjustment in the DRG certification in order to minimize the incentive to increase admissions.	12/31/85[1/]	Under discussion within HCFA.

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1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Swing Beds (Sec. 904 of P.L. 96-499)	Report of the evaluation study of the Rural Swing-Bed Program of demonstration under Medicare/Medicaid of hospitals using beds on a swing-basis as acute or long-term care beds.	12/05/83[1/] 09/30/86[2/]	Anticipate release in December, 1985.
Coordinated Audits P.L. 96-499 Section 914	1) for demonstration of coordinated appeal.	12/31/82[1]	FY 1987 legislative package contains the repeal provision.
	2) report on the overpayment collection.	12/31/81[1/]	Expect release in August 1985.
Physician-Directed Clinics (Sec. 3 of P.L. 95-210)	Physician-Directed-Clinics - Requires the Secretary to conduct demonstrations in urban medically underserved areas with respect to physician-directed clinics which employ physician assistants or nurse practitioners.	01/01/81[2/]	Demonstrations are being undertaken in five cities in conjunction with the Robert Wood Johnson Foundation. Congress notified on 12/30/80 that report would be delayed until after the completion of these demonstrations. Demon-

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Physician-Directed Clinics (Continued)			strations scheduled to end by 9/85; evaluation contractor report expected by 4/86. HCFA expects to release in January 1987.
Hospice Demonstration (Sec. 122(h)(2) of TEFRA)	Hospice Care -Requires the Secretary to report on the effectiveness of current hospice demonstration projects including: (1) an evaluation of the cost-effectiveness of hospice care, (2) the reasonableness of the 40 percent cap amount for hospice care, (3) the proposed methodology for determining such cap amount, (4) the proposed standards for requiring and measuring the maintenance of effort for utilizing	09/30/83[1]/ 04/30/85[2]/	Anticipate release in the near future.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
	volunteers, and (5) an evaluation of physician reimbursement for hospice services.		
Coverage of Respiratory Therapy Services (Sec. 958 of P.L. 96-499)	Directs the Secretary to study the need for coverage of respiratory therapy services as a home health benefit under Medicare.	12/05/82[1]/ 03/31/84[2]/	Under discussion with in HCFA.
Foot Care (Sec. 958 of P.L. 96-499)	Directs the Secretary to conduct a study involving a comprehensive analysis of the cost of foot care, including the cost effects of alternative approaches to improving coverage for specific types of foot conditions.	12/05/82[1]/	Anticipate release in the near future.

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1/ Date established by legislation.

2/ HCFA projected completion date.

1290

Report/Authority	Description	Due to Congress	Status
Hospice Benefit (Sec. 122(i)(1) of TEFRA)	Directs the Secretary to conduct a study on whether or not the reimbursement method and benefit structure for hospice care under the Medicare program are fair and equitable and promote the most efficient provision of hospice care.	01/01/86[1/]	HCFA expects release in early 1986.
Registered Dietitians (Sec. 958 of P.L. 96-499)	Directs the Secretary to study the circumstances and conditions under which services furnished by registered dietitians should be covered as a home health benefit under Medicare.	12/05/82[1/] 03/31/84[2/]	Anticipate release in the near future.
Clinical Social Workers (Sec. 958 of P.L. 96-499)	Directs the Secretary to conduct demonstration projects to determine the administrative, financial, and other aspects of making the services of clinical social workers more generally available under Medicare.	12/05/82[1/]	Demonstration contract awarded September 1982. Evaluation contract award 9/84 with final report from evaluation expected 9/86.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
AFDC Homemaker/Home Health Aide Demonstrations (Sec. 966 of P.L. 96-499, Sec. 2156 of P.L. 97-35)	Directs the Secretary to conduct demonstration projects in up to 12 States for the training and employment of AFDC recipients as homemakers or home health aides. (P.L.97-123 required that the Secretary enter into agreement with 7 States by January 1, 1982 to conduct the demonstrations). Secretary to submit annual report to the Congress evaluating the progress of demonstration projects, and to submit a final report not more than 6 months after receipt of final reports from all States participating in the project.	03/31/84 1/ (Interim) 1/82	Agreements entered into with 7 States in December 1981. Interim reports submitted to Congress in March 1982, March 1984, and January 1985. Next interim report scheduled for release in early 1986.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Health Maintenance Organizations (Sec. 2178 of P.L. 97-35, and Sec. 114 of P.L. 97-248)	Directs the Secretary to conduct a study evaluating the extent of, and reasons for, Medicaid and Medicare beneficiaries terminating membership in Health Maintenance Organizations.	Due date not established	Report in preparation. Due date not established.
HMOs/Competitive Medical Plans (Sec. 114 of P.L. 97-248)	The provision authorizes Medicare prospective reimbursement under risk sharing contracts with HMOs and other eligible organizations. The Secretary is required to conduct a study on the benefits, in addition to Medicare benefits, which are provided under the new risk reimbursement.	12/07/86	Study implementation plans being developed. Secretary on 12/7/84 notified Congress that an acceptable AAPCC methodology has been developed. GHPOS will establish a system to accumulate data for the report beginning with the effective data for the HMO provision. Anticipate release in January 1987. Report due within 24 months of the "initial" effective date, which begins either:

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Report/Authority	Description	Due to Congress	Status
HMOs/Competitive Medical Plans (Continued)			1) the first day of the thirteenth month after enactment (i.e., 9/1/84), or 2) when the Secretary notifies Congress that the methodology to make appropriate reimbursement adjustments has been developed. This was done on 12/7/84.
Home and Community-Based Services (Sec. 6 of P.L. 97-414—Orphan Drug Act)	Sec. 6(b) - Requires the Secretary to report the results of studies currently evaluating home and community based health services, and make recommendations to improve the provision of such services.	01/01/85[1/]	This report to come from information generated under Medicaid Program Evaluation contracts. Contracts awarded 9/30/83. Anticipate release in the near future.
Home Health Services P.L. 97-414 Orphan Drug Act	Sec. 6(c) - Requires the Secretary to compile and analyze the results of significant studies conducted by any public or private entity, group, or individual, related to alternative reimbursement methodologies for home health services.	07/03/83[1/] 04/30/84[2/]	Anticipate release in the near future.

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1/ Date established by legislation.

2/ HCFA projected completion date.

1294

Report/Authority	Description	Due to Congress	Status
Home Health Services P.L. 97-414 Orphan Drug Act (Continued)	Sec. 6(e)(4)- Requires the Secretary to conduct demonstrations commencing no later than January 1, 1984, to test:		
	(A) methods for identifying patients at risk of institutionalization who could be treated more cost-effectively with home health services and other non-institutional health services; and	01/01/85[1]/ 08/31/86[2]/	These studies are being conducted as part of the National Long-Term Care Channeling demonstrations currently underway. Results from evaluation contract expected late 1985. Anticipate release in June of 1986.
	(B) alternative reimbursement methodologies for home health agencies in order to determine the most cost-effective and efficient way of providing home health services.	01/01/85[1]/ 08/31/89[2]/	Contract awarded on December 29, 1983 to ABT Assoc. Inc. However, findings will not be available until June of 1989.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Impact of State Rate Setting Systems (Sec. 603(a) of P.L. 98-21)	Study examining the overall impact of State hospital payment systems on the Medicare and Medicaid programs, payments and premiums under private health insurance plans, and on tax expenditures.	12/31/86[1/]	Report under discussion within HCFA.
Medigap (Section 1882(f)(1)(c))	The Secretary is required to conduct a study and to submit to the Congress a report on the effectiveness of various State approaches to regulation of Medicare supplemental policies, and the need for additional standards.	01/01/82[1/]	Contracts for the study were awarded September 30, 1981. Congress notified 7/29/81 that report would be delayed until December 1982. Study delayed further due to problems with contracts and survey instrument. Executive Summary of Contractor report has been developed and sent to selected Senators upon request (Baucus/Dole). At this time, the release date is not known.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Physician Services to Hospital Inpatients (Sec. 603(a) of P.L. 98-21) as amended by P.L. 98-369.	Requires the Secretary during fiscal year 1984 to begin the collection of data necessary to compute the amount of physician charges for services furnished to hospital inpatients whose discharges are classified within those groups. The Secretary is to make recommendations on the advisability and feasibility of providing for payment based on a DRG--type classification for physicians' services furnished to hospital inpatients. A new due date was established by P.L. 98-369 which also makes this report separate from the PPS Annual Report.	07/01/85[1/]	Anticipate release in October of 1985.
Sole Community Hospitals (Sec. 603(a) of P.L. 98-21)	Study and make legislative recommendations to the Congress regarding an equitable method of reimbursing sole community hospitals which takes into	04/01/85[1/]	Anticipate release in the near future.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Sole Community Hospitals (Continued)	account their unique vulnerability to substantial variations in occupancy.		
Medicare Parts A & B Information Exchange (Sec. 603(a)of P.L. 98-21)	Examine ways to coordinate an information transfer between Medicare Parts A and B, particularly with respect to those cases where a denial of coverage is made under part A and no adjustment is made in the reimbursement to the admitting physician(s).	04/01/85[1/]	Anticipate release in the near future.
Uncompensated Care Costs (Sec. 603(a) of P.L. 98-21)	Report on the appropriate treatment of uncompensated care costs, and adjustments that might be appropriate for large teaching hospitals located in rural areas.	04/01/85[1/]	Anticipate release in the near future.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Information Availability (Sec. 603(a) of P.L. 98-21)	Report on the advisability of having hospitals make available information on patient care costs financed by both public programs and private payors.	04/01/85[1/]	Anticipate release in the near future.
Hospitals Outside U.S. (Sec. 603(a) of P.L. 98-21)	Study and make recommendations to the Congress on the method for including hospitals located outside the fifty States and the District of Columbia under a prospective payment system.	04/01/84[1/]	Report returned to HCFA to include comments from OS on 3/26. Anticipate release in September 1985.
SNF Shortage (Sec. 603(d) of P.L. 98-21)	Conduct demonstrations with hospitals in areas with critical shortages of skilled nursing facilities to study the feasibility of providing alternative systems of care or methods of payment.	11/30/88[2/]	At this time we anticipate the report will be submitted on time.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Skilled Nursing Facilities (Sec. 605(b) of P.L. 98-21)	Study and report to the Congress with respect to (1) the effect which the implementation of section 102 of the Tax Equity and Fiscal Responsibility Act of 1982 would have on hospital-based skilled nursing facilities, given the differences (if any) in the patient populations served by such facilities and by community-based skilled nursing facilities and (2) the impact on skilled nursing facilities of hospital prospective payment systems. Due date changed from 12/31/83 to 12/1/84 by section 2319 of P.L. 98-369.	12/01/84 2/	Report required in (1) will not be done because the single limit did not go into effect. Report required in (2) will be part of the Annual Report required by section 603(a) of P.L. 98-21. Anticipate release in July 1985.
Nutritional Therapy for Renal Disease Patients (Sec.958 of P.L. 96-499)	Study and report to Congress with respect to (1) the extent to which the use of nutritional therapy in early renal failure can retard or arrest the progression of the disease, and (2) the administrative, financial, and other aspects of making nutritional therapy generally available under Medicare.	12/05/82 1/	NIH has begun to conduct clinical trials which will take 4 - 4 1/2 years. Cost effectiveness study to begin after clinical trials. Report to be completed in approximately 5 years.

1/ Date established by legislation.

2/ HCFA projected completion date.

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Report/Authority	Description	Due to Congress	Status
Waivers of Percentum Reductions to States Not Meeting Requirements for Mechanized Claims Processing and Information Retrieval Systems: P.L. 96-398	This report identifies any waivers granted to States whereby a percentum reduction would not apply and describes the basis for each determination.	No date specified. Report can be submitted as necessary.	This report is completed only when we have information to report.

1301

1/ Date established by legislation.

2/ HCFA projected completion date.

1301

HCFA RELATED STUDIES AND REPORTS REQUIRED BY P.L. 98-369
"THE DEFICIT REDUCTION ACT OF 1984"

Report/Authority	Description	Due to Congress	Status
Outpatient Diagnostic Laboratory Test Section 2303 P.L. 98-369 DEFRA	Report on the advisability of continuing a fee schedule for hospital-based laboratories serving hospital outpatients.	01/01/87	GAO has responsibility for this report.
Physician Laboratory Fees P.L. 98-369 DEFRA	Report to the Congress with respect to the feasibility of making direct payment of laboratory fees to physicians, the basis for a formulation of a nationwide fee schedule, and appropriate indexing mechanism.	01/01/87	Anticipate timely release of the report.
Pacemaker Payment Review Section 2304 P.L. 98-369 DEFRA	Review and report to the Congress regarding the appropriateness of the amounts recognized as reasonable under Medicare part B for physicians' services associate with implantation or replacement of pacemaker and pacemakers leads.	03/01/85	Anticipate release in the near future.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Physician Reimbursement Section 2306 P.L. 98-369 DEFRA	Monitor physicians' services in order to determine any changes in the per capita volume and mix of services provided to beneficiaries under Medicare Part B. The report should include legislative recommendation on how to restrict growth in Part B program costs without these costs being transferred to beneficiaries.	01/01/85	Anticipate release in September 1985.
Nonlabor DRG Component Section 2311 P.L. 98-369 DEFRA	Review the urban/rural payment differential with respect to the advisability of making adjustments in the nonlabor component of those DRG's which have high fixed nonlabor costs.	January 1985	To be included in report on urban/rural rates required by 603(a) of P.L. 98-21. as part of 1985 PPS Impact Report.
DRG Variation in Inpatient Costs Section 2311 P.L. 98-369 DEFRA	Study the degree of variation in inpatient costs within each DRG. The study must also present alternative means of computing payments and a discussion of the merits of a method of payment under which a percentage of the payment amount could be determined on a regional basis.	09/01/84	To be included in report on urban/rural rates required by 603(a) of P.L. 98-21 as part of 1985 PPS Impact Report.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Varying Proportions of Labor/Nonlabor Component Section 2311 P.L. 98-369 DEFRA	Study the advisability of varying by DRG the proportion of the labor and nonlabor components of the payment amounts, instead of applying the average proportion of those components to all DRG's.	January 1985	To be included in report on urban/rural rates required by 603(a) of P.L. 98-21 as part of 1985 PPS Impact Report.
Nurse Anesthetists Section 2312 P.L. 98-369 DEFRA	Study possible Medicare reimbursement methods which would not discourage the use of certified registered nurse anesthetists by hospitals.	As soon as practicable	To be discussed in Physician DRG Report required by 603(a) of P.L. 98-21. Scheduled for release in October, 1985.
Disproportionate Share Section 2315 H P.L. 98-369 DEFRA	Report to Congress identifying those hospitals that serve a significantly disproportionate number of patients who have low income or are entitled to Medicare Part A benefits.	12/31/84	Report under development, at this time the release date is not known.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Prospective Payment Wage Index Section 2316 P.L. 98-369 DEFRA	Wage Adjustment Report - To conduct a study to develop an appropriate index to adjust the Medicare prospective payment amounts to reflect area differences in average hospital wage levels, taking into account wage differences of full-time and part-time workers.	08/18/84	Report signed by the Secretary on 3/29/85.
	Hospital Wage Index - Conduct a study and include in the final report a proposed criteria by which an adjustment could be made in a hospital's wage index if such index did not accurately reflect the hospital wage levels in the labor market area serving the hospital.	12/31/84 2/	Anticipate release in the near future.

2/ HCFA projected completion date.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Prospective Reimbursement of SNF's Section 2319 P.L. 98-369 DEFRA	Required by TEFRA (P.L. 97-248) to develop legislative proposals for prospective reimbursement of SNF's. The amendment provides for a new reporting date to the Congress.	08/01/84	Anticipate release in the near future.
Options for Prospective Payment of SNF's P.L. 98-369 DEFRA	Requires the Secretary to report to Congress on the range of options available for prospective payment of SNF's. Included in the study should be an examination of the feasibility, advisability and methods of incorporating into the hospital DRG system payments for SNF services.	12/01/84	Report under development, at this time, the release date is not known.
Hospice Section 2343 P.L. 98-369 DEFRA	Requires the Secretary to study the necessity and appropriateness of the hospice "core services" requirement. The study must include analysis of Medicare certified hospice and non-medicare hospices.	01/01/86	Report is currently being developed by HCFA. Release date is not known.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

1306

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Report/Authority	Description	Due to Congress	Status
Health Maintenance Organization/Competitive Medical Plans Section 2350 P.L. 98-369 DEFRA	The provision allows an HMO to request that the Secretary withhold part of the expected Medicare payments (when the adjusted community rate of Medicare enrollees is less than Medicare payments) for use in a subsequent contract period. These funds would be used to avoid significant premium changes or fluctuation in benefits to beneficiaries from year to year. The Secretary is directed to review the use of these stabilization funds in order to make a determination as to whether their continuation will be in the best interest of the program and beneficiaries.	01/89	Report is currently being developed. Anticipate timely release of this report.
Underutilized Hospital Facilities Section 2353 P.L. 98-369 DEFRA	Requires the Secretary to report his/her findings to the Congress as to how and whether the closure and con-	03/31/85	Report under development, at this time a release date is not known.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

1307

Report/Authority	Description	Due to Congress	Status
Underutilized Hospital Facilities (Continued)	version of underutilized hospital facilities as authorized in Section 1884 of the Act could result in achieving reductions in the total cost of hospital inpatient services and total Medicare expenditures.		
Social Health Maintenance Organizations Section 2355 P.L. 98-369 DEFRA	Requires the Secretary to approve - certain waivers for a project to demonstrate the concept of social HMO at four sites within 30 days after submission of a waiver request or within 30 days of enactment in the case of waiver requests submitted prior to enactment.	Reqdires an interim report on the status of the projects by August 23, 1984. A final report is due January 1988.	Anticipate release of interim report in the near future.
Medicaid Eligibility Section 2373	Secretary required to report to Congress on the impact of the application of income and resource standards and methodologies under the case assistance programs to medically needy recipients and other noncash eligibles.	July 1985	Anticipate release of the report in September 1985.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress: column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Error Rates P.L. 98-139 (FY 1984 Appropriations-Report #98-422)	Make a thorough study of the quality control system in the AFDC and Medicaid programs, and coordinate activities with the Department of Agriculture's quality control process in the food stamp program allowing for full input from the States.	Prior to FY 1986	Report on AFDC quality control system will be submitted to Congress August 1985.
Disability Benefits P.L. 98-460 (Section 7)	Requires the Secretary to study and report on the effect of the provision permitting individuals notified of termination to elect to have disability benefits and Medicare Coverage continued through the Administrative Law Judge level of appeal.	07/01/86	SSA has the responsibility for this report.
Retarded and Developmentally Disabled, P.L. 98-527 (Section 3)	Requires the Secretary to prepare and submit a report on improving services for mentally retarded and developmentally disabled persons under Medicaid. The	04/85	ASPE has the responsibility for this report.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Retarded and Developmentally Disabled (Continued)	report must address improvements in services that will increase the independence, productivity and integration into the community of mentally retarded persons and persons with developmental disabilities.		
Clinical Trials P.L. 98-619 (FY 1985 Appropriations Report #98-911	Directs the HCFA Administrator to conduct a joint study with the Director of NIH to determine the extent to which the Medicare prospective payment system has unintended or harmful effects on hospital's willingness to participate in clinical trials.	Preliminary report due prior to submission of FY 1986 budget.	Under discussion within HCFA.
Blood Banking System	Directs that a portion of the FY 1985 research budget be used to initiate a study of the impact of the Medicare prospective payment system on the structure of the blood	No date specified	Report under development.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Blood Banking System	banking industry. This analysis should cover the impact on the demand for blood products, capital acquisition by blood centers and training of personnel.		
Alzheimer's Disease P.L. 98-619 (FY 1985 Appropriations Report 698-911)	Directs HHS to report in detail on the range of services currently available and any new initiatives planned, for Alzheimer's patients. The study should review the Medicare limitations on outpatient care and home health care, the guidelines under the social security disability program and the issue of the cost of custodial care for poor patients.	Preliminary report due prior to FY 19[illegible]	ASPE has the responsibility for this report.
Health Care Technology Assessment	Directs the Secretary to review the various agencies within the Federal government currently carrying out health care technology assessment. The report should deal with the regional agencies, including HCFA.	Prior to FY 1986 hearings	PHS has responsibility for this report.

NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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Report/Authority	Description	Due to Congress	Status
Federal Medical Assistance Percentage Formula (FY 1984 Senate Appropriations Report #98-544)	Study ways to improve the formula used to calculate the Federal medical assistance percentage (FMAP) for Medicaid funding to the States.	Due date not established.	The report is in preparation. It will be submitted when study is completed.

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NOTE: Unless due date otherwise noted with footnote 2/, the date shown in the "Due to Congress" column for all reports required by the Deficit Reduction Act is legislatively mandated.

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MEDICARE: SECONDARY PAYER FOR WORKING AGED OVER 69

Question. What percentage of the aged between 65 and 69 who are working or have working spouses now choose employer health plans over Medicare? What percentage of the eligible aged over 69 do you expect to choose employer health plans?

Answer. There is no methodology currently available to identify working aged or their spouses decisions concerning the use of employer group health insurance or Medicare. Our actuaries estimate that of those eligible, approximately 60 percent of the working aged and spouses choose employer group health coverage over Medicare.

Question. How are you able to identify the working aged and working spouses?

Answer. The working aged and working spouses are mainly identified by "self-identification." In other words, when a Medicare beneficiary receives medical services, he informs the doctor, hospital or any other supplier of covered services of his health insurance coverage under an employer group health plan. "Self-identification" most often results from the provider asking appropriate "other insurer" questions.

In those instances where "other insurer" information is not obtained, our Medicare contractors can identify many working aged via the HCFA query/reply system. When the contractor queries HCFA central office for entitlement utilization and deductible information, a "Y" trailer code is sent back indicating the beneficiary is a potential working aged beneficiary. This particular "Y" trailer lead is based upon a prior bill or payment record which indicated Medicare was secondary because of employer group health plan coverage, or Social Security Administration (SSA) records which reflect that the beneficiary's retirement benefits are in suspended payment status because of earned income.

In addition, we are working on two pilot projects to assist us in identifying the working aged and working spouses. One project is with SSA and it is intended to obtain information about employer group health plan coverage at the time the beneficiary applies for retirement or survivors insurance benefits and/or Medicare. Information for those beneficiaries with employer group health benefit plan coverage will be transmitted to the appropriate Medicare claims processing contractor. This project is still in the preliminary stages of forms and instructions preparation.

Our other pilot project involves data matches between Medicare contractors' private insurance files with their Medicare beneficiary files. When a match is found, the contractor's Medicare beneficiary file will be annotated as an alert for future processing.

Question. How have you informed employers and providers of recent changes in the Medicare laws with respect to the working aged? How do you plan to do this in the future? How are you monitoring compliance with these laws?

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Answer. HCFA has informed providers of recent changes in Medicare through manualized instructions. In addition, our Medicare contractors have taken an aggressive approach informing their providers about Medicare as a secondary payer. In the very near future, HCFA plans to make available a Medicare Secondary Payer (MSP) training film to be shown to hospital admitting and billing clerks and other appropriate audiences. The film will provide information on the secondary payer provisions to encourage provider identification.

HCFA is not responsible for informing employers about MSP or monitoring their compliance with recent changes in the law. Rather, this is the responsibility of the Equal Employment Opportunity Commission (EEOC). The EEOC is responsible for implementing the Age Discrimination in Employment Act which requires that all employers with 20 or more employees must offer workers and their spouses with dependents in the 65 through 69 age group, the same health insurance plan it provides for younger workers.

HCFA is monitoring compliance with the MSP provisions in several ways. To make certain our contractors are implementing the MSP provisions, our regional offices are responsible for completion of a progress review for each contractor several times throughout the year. The progress review will pinpoint contractors not implementing certain procedures, workload and system problems, as well as staffing and budget needs. Possible action that can be taken as a result of the review is reallocation of funds from nonperformers to those who are making better efforts.

Contractors have also been given a working aged dollar goal as part of its Contractor Performance Evaluation Program (CPEP). If the contractor does not obtain its goal, it can contribute to its removal from participation in the Medicare program. Therefore, there is incentive for the contractor to implement the working aged MSP provision.

Intermediaries are required to monitor at least one hospital per quarter which shows indications of not implementing MSP. Upon completion of its review the contractor is obligated to propose corrective procedures, the implementation of which it will closely monitor.

Question. Do you believe the existing and proposed requirements may create disincentives for employers to hire the elderly due to the additional costs involved?

Answer. By amending the Age Discrimination in Employment Act (ADEA) in TEFRA and DEFRA, Congress clearly indicated its intent to prohibit discrimination against the elderly. This Administration supports vigorous enforcement of ADEA.

We have no evidence to show that the Medicare secondary payer provisions have created employment problems for the working aged. Because this group is less than 1 percent of the total work force, it is unlikely that the provisions making Medicare secondary payer to their employer group health insurance would cause employers to discriminate against them.

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Questions Submitted by Senator Ted Stevens

Dr. Davis, the State of Alaska Commissioner of Health and Social Services has written you seeking clarification of the proposed cap on Medicaid spending. Although these questions are couched in Alaska-specific terms, I believe many of the issues raised by Commissioner Pugh merit the attention of the Committee as other States in the Nation may have similar concerns about the implementation of the proposed cap. Please provide the Committee with your responses to the following questions:

Question. At present 40 States offer a broader set of medical services under their Medicaid Programs than Alaska. A CAP as proposed by President Reagan would place Alaska's "bare bones" program in serious jeopardy while other States could eliminate or reduce less essential medical services. Will there be any mechanism to achieve a minimum level of equity across the nation so that all States can insure their Medicaid recipients a responsible level of medical care?

Answer. The "Cap" on Medicaid will be implemented by the States in a variety of ways depending on choices that the States make. We intend to remove a number of requirements that now restrict the States' flexibility to tailor their programs to their individual needs. The resulting increase in flexibility should permit the States greater scope for improving the cost-effectiveness of their programs. It is our opinion that the FY 1986 funding level, which is approximately 5 percent less than the current law requirements, will not require the States to make significant reductions to those beneficiaries who are currently eligible for Medicaid.

The States have demonstrated great creativity adapting to the reductions in the Federal Medicaid payments between 1982 and 1984. The FY 1986 budget request would give the States strong incentives to continue efforts to manage their programs cost-effectively. For example, we estimate that the current Medicaid eligibility error rate of 2.7 percent represents over $400 million a year in erroneous expenditures and that uncollected payments from third-parties total $500 million a year. More determined efforts by States in these areas, for instance, could afford substantial savings.

Question. Alaska's percentage of elderly in the general population is still increasing at a significant rate. At the present time there are an estimated 16,000 persons over the age of 65 in Alaska. By 1991 the over age 65 population is expected to be 22,000 persons. Clearly, Alaska is faced with a need for additional long term care beds over the next five years. Several Certificates of Need are before the State of Alaska at the present time for new bed construction. In addition, Alaska's Home and Community Based waiver application is currently before your agency for consideration. We are expecting a response to our Waiver Application in March. Will President Reagan's proposed Medicaid CAP for FY 86 accommodate the needed growth in our long term care delivery system for both new beds and for implementation of a Home

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and Community Based Services waiver program? It is extremely critical that Alaska understand President Reagan's proposal with respect to funding for the Waiver and essential growth in our long term care industry.

Answer. The FY 1986 Medicaid budget allows for growth in Medicaid costs at about 5-6 percent a year. The FY 1986 Medicaid budget level is 5 percent above the FY 1985 level. Future years would be increased by the rate of change in the Medical Consumer Price Index.

The Home and Community Based Waiver (HCB) program has been very popular with States as they have tried to experiment with alternative ways to care for those in need of long term care services. The specific details for the Medicaid Cap are not yet finalized. However, the area of HCB waivers is clearly an area which is being addressed in our attempts to provide the States as much flexibility as possible to control their program growth without sacrificing needed services.

Question. At the present time State Medicaid programs must accept billings from the Indian Health Services (IHS) for treatment of Medicaid eligible Natives at IHS facilities. These Medicaid funds are then reallocated within the IHS system nationwide to pay for facility maintenance and improvements. If a CAP is placed on State Medicaid expenditures in FY 86, is it President Reagan's intent to similarly cap the share of each State's Medicaid budget that IHS may claim? Obviously, failure to impose such an IHS CAP would leave States' Medicaid budgets vulnerable to serious erosion by permitting IHS spending plans to consume an ever increasing share of State Medicaid expenditures.

Answer. Federal Medicaid spending on Indian Health Service (IHS) is matched by the Federal government at a 100 percent rate under current law. The amount paid in FY 1983 was approximately $10 million for these claims or 1/2 of one percent of total program expenditures. The maximum State expenditure for IHS claims is 3.2 percent. Therefore, the impact of this arrangement will not be large.

Question. While President Reagan's FY 86 Medicaid proposal provides for an annual escalator to the CAP based on a medical price inflator, there does not appear to be an adjustment for the expanded population of new eligibles that will be entitled to Medicaid each year. The most significant area of concern is the increase in aged, blind, and disabled recipients of Supplemental Security Income and State Supplemental Payments. This increase in the eligible population will continue to confront states under proposed Federal policy for FY 86.

Answer. We gave the allocation procedures for the Medicaid Cap considerable thought before we selected the option of using the latest actual expenditure data to determine the proportional distribution of funds in FY 1986. This choice avoids the substantial uncertainties involved in attempting to estimate future demand and the variables that may affect it. Possible increases in supplemental recipients are of concern, but a variety of other possible changes -- such as changes in the tax bases, in the overall size of the indigent population, and in State per capita income -- are also arguably important to account for such factors.

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The effects of each of these factors would require development of consistent estimates on a State-by-State basis. In many cases, the data needed to develop such estimates are not reliable or not even collected at a State level. Therefore, using data that reflects the most recent actual experience of the States is preferable.

Question. Finally, President Reagan is proposing a similar CAP on Medicaid administrative expenditures in FY 86. Alaska is currently engaged in the preliminary phase of procuring a Medicaid Management Information System (MMIS) by July 1, 1986 to replace our expiring contract with Computer Science Corporation. Since MMIS systems are eligible for 90 percent federal funding during development, and 75 percent federal funding for on-going operations, our plan will increase the share of Federal funds that Alaska will be entitled to in FY 86 (development period) and later years (operational period). Does President Reagan's CAP provide the flexibility for Alaska to make this transition to an MMIS system to count on the Federal funding that would be needed to support it?

Answer. The administrative grant proposal will limit Medicaid administrative costs in FY 1985. Each State's share of this grant would be held constant at the same proportion of payments received in FY 1984. This proposal is within the context of a major effort to control Federal spending. As with any major policy change, some related problems may arise because of the timing of the action. Alaska's transition to a modern computer system represents an important administrative step for the State. While the timing of this step may present some difficulties given the introduction of the CAP, the additional flexibility that is a part of the proposal afford opportunities for administrative cost savings in a variety of areas.

Questions Submitted by Senator William Proxmire

UNEXPECTED DEATH STATISTICS

Dr. Davis, one subject of medical research that seems to be getting a good deal of attention lately is sleep disorders. I'm told that unexpected deaths often occur during the hours of deep sleep when the body's vital functions are at a low ebb. I'm also told that research on this subject would benefit greatly from information regarding the clock time of unexpected death in hospitals.

Question. Can you tell us if this kind of data is being routinely collected through the DRG program or whether it would be possible for a researcher to mine Medicare records for this information?

Answer. Sudden and unexpected death during sleep is also known as the Sudden Infant Death Syndrome (SIDS). Standard coding procedures would not indicate whether a sudden death in an adult occurred during sleep. The number of infants covered under the Medicare program is exceedingly small and would not be a suitable base for research in this area; although a significant number of

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SIDS deaths probably do occur among Medicaid beneficiaries, Medicaid is not included in the Health Care Financing Administration's DRG program.

NEW TECHNIQUE

Question. Last August an article appeared in the Chicago Tribune describing a technique for detecting whether or not a spot on the lung is benign or malignant without the use of exploratory surgery. The technique, which is being used at 22 medical centers across the country, could make unnecessary up to 20 percent of exploratory surgery for solitary lung spots. Does HCFA have a mechanism for distributing information on new techniques such as this --which could save millions of Medicare and Medicaid dollars --to practicing physicians?

Answer. HCFA does not distribute information to practicing physicians concerning new techniques although one of the functions of PROs is to educate physicians and hospitals about changes in practice and new technologies. HCFA does make an effort to identify major new technologies while they are still in the investigational stage, so that determinations to cover them can be made as promptly as possible after they have moved beyond the experimental stage. Decisions concerning Medicare coverage of new technologies are published in the Medicare program's national manual system.

We should point out that other parts of the Department of Health and Human Services do undertake to bring major new technologies to the attention of practicing physicians. For example, the National Institute of Health has a program of National Consensus Conferences which disseminates information on medical advances; the National Cancer Institute provides rapid access to information via telephone and computers. Also, the National Library of Medicine's computerized data bases make such information very highly accessible to practicing physicians.

DIRECT TRANSMISSION OF MEDICARE DATA

Apparently Medicare data is transmitted directly to HCFA and indirectly under contract with the Blue Cross Association of Chicago. The Inspector General believes you could save $12.5 million over the next seven years if you redesigned your telecommunications network so that all data is transmitted directly to HCFA.

Question. Do you intend to implement this recommendation?

Answer. We agree with the Inspector General that the cost of the telecommunications network can be reduced. We are negotiating with the Blue Cross Association to reduce costs. It may be possible to achieve the savings identified by the Inspector General without redesigning the entire telecommunications system.

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THIRD PARTY MEDICAID COVERAGE

Dr. Davis, according to a GAO report dated February 12, HCFA estimates that Medicaid is paying $500 million to more than $1 billion annually for medical services that insurers should cover. GAO pointed out that you focused your oversight of State practice in this area on compliance reviews but that you had not gotten States to adopt suggested improvements because there were no specific regulatory standards on how States should identify and use Medicaid recipients' insurance resources. GAO also indicated that you dropped your quality control program in 1982 and thus States were not faced with the choice of going after insurance companies more aggressively or losing Federal Medicaid payments.

Question. Have you decided to reinstate your quality control program or to promulgate more specific regulatory requirements as recommended?

Answer. The measures we have taken in the past (quality control, compliance reviews, offers of technical assistance) have been only partially successful in encouraging States to improve their Third Party Liability (TPL) programs. We recognized this before the GAO published its final report and welcome the attention their findings bring to this important area.

We have launched a three-pronged approach to improve Medicaid TPL:

- Provide incentives and technical assistance to the States to improve performance.
  - o Issue "TPL Successful Practices Guide" to encourage State-to-State assistance.
  - o Provide a system design document to automate TPL operation through State Medicaid Management Information System.
  - o Initiate cooperative project with SSA to improve quality of TPL information collected from Supplemental Security Income applicants.
- Impose additional requirements and take punitive measures for deficient performance.
  - o Initiate a TPL audit program in FY 1985 --Third Party Recovery Audit Coordinated Effort (TRACE).
  - o Strengthen TPL regulations.
  - o Require Cost Avoidance as principal TPL approach.
  - o Require that medical support be included in child support orders from absent parents.
- Strengthen Federal oversight of State TPL operations.
  - o Conduct periodic inventory of State TPL programs.
  - o Collect TPL financial data through a revised quarterly expenditure statement.

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INTERNAL CONTROLS

Dr. Davis, I understand that HCFA has not as yet developed a comprehensive plan to evaluate internal controls over Medicare and Medicaid benefit payments. I also understand that the Department's Inspector General with the concurrence of the Assistant Secretary for Management and Budget recommended that HCFA include internal control reviews as part of its 1986 contract negotiations with insurance companies making payments on behalf of Medicare beneficiaries.

Question. What are your plans for evaluating the adequacy of your internal controls over Medicare and Medicaid payments?

Answer. HCFA plans to evaluate the adequacy of its monitoring of internal controls over payments made on behalf of Medicare and Medicaid beneficiaries. These evaluations will be conducted in one of the following ways:

- scheduling and conducting internal control reviews (ICR);
- requesting and obtaining independent audits;
- scheduling and conducting thorough management reviews;
- taking corrective action based on evaluations of vulnerability assessment (VA) results; or
- substituting "ongoing" activities/reviews for ICRs provided they meet the guidelines for ICRs.

These evaluations of the internal control areas (ICA) responsible for monitoring the Medicare and Medicaid programs will be initiated as part of HCFA's implementation of the revised HHS Internal Control Program as follows:

- Under Medicare, our internal control efforts will encompass both Medicare ICAs and Medicare contractors. The Medicare contractors were included because they are responsible for administering the Medicare program as agents of HCFA and are, therefore, subject to the Federal Manager's Financial Integrity Act (FMFIA). As part of the process, we will evaluate the Medicare ICAs within HCFA (Central and Regional Offices) to determine if they have adequate controls over payments made by Medicare contractors on behalf of Medicare beneficiaries. In addition, Medicare contractors will also be evaluated.
- Under Medicaid, our internal control efforts will be limited to the Medicaid ICAs within HCFA (Central and Regional Offices). This is because Medicaid is a joint Federal/State program which is administered by each State. Since the State agencies are not agents of HCFA, they are not subject to the FMFIA. Consequently, our evaluation will not extend into State controlled operations.

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In accordance with the revised HHS Internal Control Program, HCFA is in the process of developing a new internal control inventory that will cover all significant administrative functions and programmatic operational activities including automatic data processing; Medicare, Medicaid, and PRO monitoring; and the Productivity Improvement Program (A-76). Once the inventory has been developed, HCFA will conduct a VA of each ICA listed in the inventory. The VA process will determine the priority for scheduling ICRs in Fiscal Years 1986 and 1987. ICAs with a high or moderate vulnerability rating will be scheduled for review on a priority basis. In certain circumstances, HCFA management may decide that other actions are more appropriate than conducting an ICR, e.g., requesting and obtaining an independent audit, scheduling and conducting a thorough management review, substituting an "ongoing" activity/review, etc.

HCFA is scheduled to complete the segmentation process (development of the new internal control inventory) by June 30, 1985, VAs by September 30, 1985, and the HCFA Internal Control Review Plans for FY 1986 and 1987 by October 1, 1985. Based upon the FY 1985 schedule for implementing the revised HHS Internal Control Program, the evaluation of the ICAs responsible for the monitoring function is planned for FY 1986.

Question. What role does HCFA plan for Medicare contractors in reviewing their own internal controls?

Answer. HCFA plans to require the contractors to establish an internal control review program. As part of the FY 1986 contract negotiations, HCFA will amend the Medicare prime contract effective October 1, 1985 to require compliance with the Federal Managers' Financial Integrity Act (FMFIA). In accordance with the existing contract provisions, HCFA and the Medicare contractors will jointly develop the necessary operating procedures.

HCFA will require the contractors to send reports to the HCFA regional offices on the effectiveness of their system of controls. The reports will identify any internal control weakness(es) found and describe plans for corrective action or state that they cannot correct the weakness(es) because it is outside their scope of authority. The HCFA regional offices will review and analyze the contractor reports for adequacy in light of ICR guidelines, budget limitations, and cost/effectiveness. The regional office will identify and track the correction of those weaknesses which merit action in accordance with the criteria for adequacy.

SECOND SURGICAL OPINIONS

Dr. Davis, the attachment to your March 19 letter indicated you disagree with the Inspector General's recommendation to implement a mandatory second opinion program for Medicare because that recommendation is based on an assessment of a Medicaid mandatory second opinion program that dealt with a much younger population. Apparently none of the work you supported has looked at the impact of a mandatory second opinion program on those over the age of 65.

Question. Don't you think it was a questionable decision to

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spend $2.5 million on an evaluation of second opinion programs without specifically examining the impact of mandatory second opinions on the cost of medical care to the elderly?

Answer. No, I do not. The decision to proceed with a voluntary, rather than a mandatory Medicare second opinion demonstration was made in 1977, not because we did not recognize the value of a mandatory experiment, but because legal considerations precluded, and still preclude, a mandatory second opinion demonstration. In addition, we believe it was important to assess the cost-effectiveness of voluntary second opinion programs and the impact of financial incentives in voluntary programs. In 1977, it was not clear whether these programs could be effective.

The intent of HCFA's Medicare demonstration authority, principally Section 222 of the Social Security Act, limits our ability to conduct experiments that may be perceived as reducing Medicare benefits (e.g., surgery would not be reimbursed if a second opinion was not obtained) and that would require all beneficiaries in a given geographical area to participate. In 1980, Congress attempted to pass legislation to give HCFA the authority to conduct mandatory Medicare Second Surgical Opinion Program demonstrations. This proposal, authored by the Congressman McGuire of New Jersey was not enacted.

We believe that the decision to evaluate the voluntary Medicare SSOPs in New York and Michigan, the mandatory Medicaid SSOP in Massachusetts, and HCFA's national second surgical opinion program public information campaign was the correct decision, and has provided valuable information to State Medicaid directors, to HCFA, and to the private sector concerning the value of second opinion programs in reducing rates of elective surgery.

OTA REPORT ON KIDNEY DIALYSIS

Dr. Davis, in December, the Office of Technology Assessment came out with a case study of the hemodialysis equipment and disposables industry. The study found that a major issue facing the industry was dialyzer reuse. If 50 percent of patients reused dialyzers, the savings could be $80 million a year. At present, according to the study, medical opinion views reuse as an acceptable practice as long as the reprocessing is done with appropriate care, although some have expressed concern about possible adverse consequences for patients.

Question. Is HCFA supporting any research into the safety and efficiency of dialyzer reuse which might lead to a reduction in the cost of hemodialysis to the government?

Answer. The issue of the safety and efficacy of dialyzer reuse is properly a medical issue and not entirely within the purview of HCFA. However, there is considerable evidence that reuse of dialyzers has been shown to be safe and efficacious.

- The National Institute of Arthritis, Diabetes, Digestive and Kidney Diseases (NIADDKD) funded a clinical trial into the reuse of dialyzers which was completed in June of 1981. In Congressional testimony NIH stated that the issue of reuse is no longer a clinical issue, but an economic one.

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- In 1983, a national workshop on the Reuse of Consumables in Hemodialysis concluded that overall there is only, "a small but finite risk of morbidity and negligible or no risk of mortality with reuse in the immediate treatment setting."

- Since 1976, the Center for Disease Control (CDC) each year conducts, with HCFA cooperation, a national surveillance of dialysis-associated hepatitis and other diseases in the United States. To date, the survey has found no relationship between the reuse of dialyzers and the incidence of hepatitis among both patients and staff. In fact, the incidence of hepatitis was significantly lower in 1980, 1982 and 1983 than it was in 1976 despite a dramatic increase in reuse among facilities. In 1976 18 percent of centers reused dialyzers. This has increased to 28 percent in 1981, 43 percent in 1982 and 52 percent in 1983.

- The National Kidney Foundation (NKF) has published standards for dialyzer reuse. Interim standards were first approved in June of 1982. The revised standards were approved in December of 1983. The president of the NKF has stated, "The National Kidney Foundation Revised Standards for Reuse represent the only widely approved and published Reuse Standards in existence. They are readily achievable and represent the present state of knowledge and technology. If carefully observed, they offer facilities, staff and patients assurance of safe, effective dialysis."

In terms of the economic impact of reuse, HCFA is already achieving savings due to dialyzer reuse. A study conducted by the Urban Institute under a grant with HCFA concluded that costs in centers reusing dialyzers were up to $1,000 less per patient per year compared to centers not reusing dialyzers.

This cost differential has been included in the calculation of the composite rates for dialysis which were put into effect in August of 1983. Therefore, the current dialysis payment rates are lower than they would be in the absence of dialyzer reuse.

KIDNEY DIALYSIS

On February 1, the General Accounting Office came out with a report on the end stage renal disease program that recommended a change in physician payment rates because patients receiving dialysis at home were not being seen by physicians as often as HCFA assumed in setting the payment scale. GAO estimated that such a change could save the government $11.8 million annually.

Question. Are you in the process of revising your monthly capitation payment system as recommended by GAO?

Answer. We are taking into consideration this recommendation and the data developed in the GAO report. At this time we are evaluating this report along with studies for HCFA in order to determine if there should be a reduction in the monthly capitation payment to physicians for their outpatient maintenance dialysis services.

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SECOND SURGICAL OPINIONS

Dr. Davis, last year, in a response for the record, you indicated that the final results of an evaluation of voluntary and mandatory second surgical opinion programs were due in June of 1984. However, in an attachment to a letter you wrote me one week ago, you indicated that HCFA is currently evaluating the study results.

Question. Why has it taken so long to come to grips with these results?

Answer. We received the draft final report from the evaluation contractor, Abt Associates, Inc. on December 9, 1984. Unanticipated complexities in the surgery rate analysis resulted in a 6 month delay. In addition, we had this draft final report reviewed by the Office of Research and Demonstration's Policy Center at the Rand Corporation.

Based on comments received from Rand and HCFA ORD staff, Abt Associates made revisions and the the final report was received April 2, 1985.

Question. When will HCFA have completed its evaluation and be in a position to make a final determination on the wisdom of requiring second surgical opinions?

Answer. Based on the final evaluation report received April 2, 1985, we have determined that it is unreasonable to generalize findings from the mandatory Massachusetts Medicaid Second Surgical Opinion Program (SSOP) experience. We do not agree with the recommendation of the Department's Inspector General that HCFA, on the basis of these findings, proceed to implement a national mandatory Medicare SSOP. Moreover, study results relate to a period prior to the implementation of Peer Review Organizations (PROs). We strongly believe that the pre-admission screening of targeted elective surgical procedures by PROs may accomplish the objective of reducing unnecessary elective surgery in the Medicare program without incurring the administrative costs of a mandatory Medicare SSOP and the possible inconveniencing of Medicare beneficiaries. While we do not favor implementing a mandatory SSOP for Medicare at this time, we will, of course, continue to consider new information and studies which examine SSOPs.

SECOND OPINION SURVEY

Dr. Davis, a New York hospital - Cornell Medical Center survey found 14 percent of recommendations for elective surgery were not confirmed when patients asked for a second opinion under a mandatory program. The survey covered 5,000 patients over an 18 month period ending in July of 1983.

Question. Are you aware of this survey and are you analyzing the results?

Answer. I presume this work was conducted by Dr. Eugene

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McCarthy. Dr. McCarthy and his associates completed a second surgical opinion study under a HCFA contract in 1981. We have not funded any of his efforts since. These results relate to research done after Dr. McCarthy's obligations to HCFA ended and to the best of my knowledge Dr. McCarthy has not shared the results of this follow-up research with us.

MEDICARE BENEFICIARIES IN WISCONSIN

Dr. Davis, many Wisconsin Medicare beneficiaries are concerned with the long delays they experience in receiving their so-called EOMB Form (Explanation of Medicare Benefits Form). As I understand the problem, these beneficiaries cannot get their private supplemental insurance to cover their $400 Medicare deductible until they receive their EOMB statement from your Baltimore office. So they find themselves in the position of hospitals sending them dunning notices for the unpaid deductible but their own insurance carriers won't pay until the beneficiary can produce their EOMB form.

Question. Are you aware of this problem? What are the steps necessary for HCFA to produce this form and what can be done to ease these problems?

Answer. HCFA centrally prepares the "Notice of Utilization" for hospital inpatient services received by the beneficiary. All disallowance notifications for either inpatient or outpatient services are prepared by our contractors.

The notice prepared by HCFA in Baltimore, for inpatient services is contingent upon: receipt by the contractor of a billing record from the hospital; completion of contractor processing forwarding of the billing records to HCFA; and HCFA processing and posting the records to the HCFA master files and generating the "Notice of Utilization"

Because of the steps involved in this process the average processing time is about 60 days.

We are concerned about the amount of time involved in the preparation of the "Notice of Utilization" and have been studying ways to reduce the time span. Ideally, the solution would be to have our contractors produce the "Notice of Utilization" when they approve payment for a bill. However, several significant changes will have to be made in the total claims process before that will be feasible. We currently have plans under way to make the changes, but because they are extensive changes that will affect providers, intermediaries and HCFA centrally, the changes will take at least 2 years to accomplish.

In the interim, in February 1985, we implemented a change in the manner in which HCFA processes the posting of billing records. This change will make possible the faster release of the "Notice of Utilization" for a significant portion of all bills processed. This will reduce the overall procesing time for all bills.

Question. Dr. Davis, as you know there was a great deal of concern among home health care providers regarding the reporting

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form #443. Without attempting to re-hash the fight over that proposed form, can you give me an idea of the type of information about home health services that we do not currently collect that you think is indispensible? Obviously, we must get a handle on the exploding costs in this area but what information is essential that is not collected on your current reporting forms from home health agencies?

Answer. HCFA has developed a new medical information form to be used in conjunction with review of home health claims. The new form will be implemented for starts of care and recertifications due after August 31, 1985.

HCFA staff (central and regional office) met with home health industry representatives and intermediary personnel on March 12-14. The form has been redesigned and definitions/instructions clarified, based on discussions at that meeting. HCFA found that intermediary decisions were not consistent and that fiscal intermediaries' review of home health claims needed to be augmented by better documentation. In fact, several studies have revealed that intermediaries are inappropriately paying for noncovered services.

The new form will lead to more accurate decisions by intermediaries, consistency in decision making by intermediaries, and comparable data across intermediaries for analysis.

Some specific examples of information to be reported on the form include the reason the patient is home bound, functional limitations, treatment plan, prognosis, patient progress and date patient was last seen by a physician.

Question. The Deficit Reduction Act directed HCFA to reduce the number of home health agencies to no more than ten. How far along is that effort? And can you provide now, or for the record, a listing of the criteria that were used to select the ten intermediaries? And, finally, was there any public input in to that criteria?

Answer. The reduction to 10 or fewer intermediaries will impact on a significant number of home health agencies (HHAs). For this reason on April 10, 1985, we published a Proposed Notice in the Federal Register announcing our reconfiguration plans and tentative selection of intermediaries.

The major criteria used included intermediary electronic data processing capability; and past performance as measured by the FY 1983 Contractor Performance Evaluation Program.

In addition, we evaluated each intermediary's performance specific to servicing HHAs in the following areas: ensuring that coverage and payment requirements were met; ensuring that correct utilization determinations were made; establishing interim payments for participating HHAs to approximate Medicare reimbursable cost as closely as possible; accurately applying principles of reimbursement to ensure that only reasonable and allowable cost of furnishing covered services to Medicare beneficiaries were reimbursed to HHAs; completing accurate coverage compliance

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reviews; completing timely HCFA cost report settlements; and processing reconsideration requests timely and accurately.

Finally, we attempted to evaluate an intermediary's performance in the area of provider relations. That is, we tried to determine whether the intermediary provides adequate training to providers, whether it responds to telephone and written inquiries from HHAs promptly and whether it demonstrates a willingness to communicate coverage and reimbursement policies fully to HCFA providers. In this area, we considered the unsolicited comment received from some HHA associations as well as individual HHAs.

The Proposed Notice was published on April 10, 1985 and the general public has until June 10, 1985 to comment. After the close of the comment period, we will publish a final notice, which will contain an analysis of the comment and the final designators.

Questions Submitted by Senator Daniel K. Inouye

RESEARCH AND DEMONSTRATION PROJECTS

Research, demonstration projects and evaluations within HCFA generate information to formulate more effective methods of managing Medicare and Medicaid programs. In order to offset long-term institutional care for the terminally-ill patient, what types of research/demonstration projects have been conducted to examine cutting Medicare and Medicaid costs by utilizing home care facilities? Were there any demonstration projects which dealt with training family members to facilitate care at home? Since long-term and Hospice demonstration projects are near completion, phase out funding has been initiated. What are the results of these projects?

Question. In order to offset long-term institutional care for the terminally-ill patient, what types of re-search/demonstration projects have been conducted to examine cutting Medicare and Medicaid costs by utilizing home care facilities? Were there any demonstration projects which dealt with training family members to facilitate care at home? Since long-term and Hospice demonstration projects are near completion, phase out funding has been initiated. What are the results of these projects?

Answer. The Health Care Financing Administration (HCFA) has conducted a number of demonstration projects which have tested the hypothesis that the provision of in-home and community-based services can delay or prevent the institutionalization of the frail elderly. While a number of these projects were completed during the past year, several major demonstration efforts in this area and/or their evaluations are underway currently (i.e., National Channeling Demonstration, AFDC Homemaker/Home Health Aide Demonstration). Preliminary findings from an evaluation of the demonstrations indicate that overall cost savings may be achieved when clients are selected for community-based programs from a population which is at immediate risk of institutionalization. In contrast, when institutional use was unlikely to occur and special program services, including case management, are received, the special services become add-on costs rather than substitute costs. Not all

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the community long term care demonstration programs identified and focused their primary efforts on this "at-risk" population as their target group. Some of the demonstrations were designed to serve individuals who are less impaired, and not necessarily nursing home bound. Thus, for most community-based service programs (e.g., in-home supportive services, adult day health, residential housing), one of the most critical tasks is to define the target population which the program intends to serve. The definition of the target population can have a very serious impact on program operations and program outcomes. In short, serving a more (or less) impaired group of clients than intended can significantly alter the client and cost outcomes of a community-based long term care program.

Hospice

HCFA conducted a national demonstration at 26 hospice sites in order to study and compare the cost-effectiveness and quality of conventional care for the terminally ill and hospice care. This demonstration began in October 1980 and ended March 31, 1985. The demonstration sites included hospital-based and community-based hospices. The final report of the HCFA Hospice Demonstration is undergoing final clearance within the Department and will be transmitted officially to Congress by the summer of 1985.

Family Training

Many of the community care demonstrations mentioned above have utilized home health agency services which provide some training to family members as part of their regular services.

In addition to these undertakings, HCFA has two ongoing demonstration projects designed specifically to test the effectiveness of providing assistance to families with individuals at risk of institutional care, including those with terminal illness.

- The University of Washington project, entitled "Alternative Family Support Strategies," provides three types of support to families:

  1. Paid respite care, up to a maximum dollar limit per family, provided by a home health agency, an adult day care center or a skilled nursing facility.

  2. Training of family caregivers and case management.

  3. Training and case management in conjunction with paid respite care.

Currently 400 Medicare beneficiaries and their families are receiving project services.

- The goal of the "Respite Care Co-op for Impaired Elderly" is to develop a model cooperative which provides respite for family caregivers of impaired elderly. HCFA is funding the South Central Commission on Aging in Kalamazoo, Michigan for 3 years to establish between seven to ten co-ops with a maximum of 10 participant families in each. The model utilizes a cooperative committee composed of impaired elderly, their family caregivers

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and representatives from community agencies. The committee, with a program coordinator, works to establish policies and procedures and to recruit families to participate. In a fashion similar to babysitting co-ops, family members pay for care received with care given.

HCFA's cooperative agreements and grants solicitation for fiscal year 1985 also includes as a priority area, projects which evaluate the effects of innovative State or local programs to promote home care by families or by other community support arrangements.

Questions Submitted by Senator Lawton Chiles

Question. Why has HCFA taken more than 3 years to finalize regulations regarding Medicaid home and community-based services?

Answer. As you know, the final regulations governing the program were published on March 13, 1985. I agree that the regulatory development was protracted in spite of our concerted efforts to expedite publication. I would attribute the principal cause for delay to our concern that these regulations provide better fiscal and quality control of the program. As development of the rules progressed, it became increasingly evident that the program was growing more quickly than expected and that not all waiver programs were successful in achieving the statutory goals of the program. The regulations were redrafted on several occasions to improve our capacity to assure the cost-effectiveness of these programs and better protect the health and welfare of waiver clients.

Question. Can HCFA provide data on the number of applications submitted, applications approved, and the length of time applications are pending by Federal fiscal year? Can you explain why application delays have increased in the past 18 months?

Answer. HCFA has received 44 waivers in FY 1982, 56 in FY 1983, 35 in FY 1984 and 18 in FY 1985. HCFA has approved 19 waivers in FY 1982, 33 in FY 1983, 26 in FY 1984 and 18 so far in FY 1985. We do not have data on the length of time waiver applications are pending. However, 1915(f) of the Social Security Act requires that a waiver must be approved, denied or additional information requested within 90 days of receipt or the request will be deemed granted. HCFA has met this requirement in all cases. We are not aware that waiver application delays have increased in the past 18 months but it is possible that delays in a particular State could be attributed to the time it took for the State to respond to our additional information request. In our view the quality of the incoming waiver request has a significant bearing on the total time needed by HCFA to reach a final decision. To aid States in this regard, we have provided them with a copy of the review guide we use in processing these waiver requests.

Question. With regard to the waiver population restriction to the number of vacant nursing home beds contained in the recently published final regulations, won't the States' waiver populations be reduced over time if they properly control the construction of

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nursing home beds and maintain low bed vacancy rates? In other words, the more successful a State is in diverting a nursing home eligible population to community placements, the fewer vacant beds that State will have. This, however, will result in a reduction in a waiver population and the future need for more beds because of the waiver funding limitation. Florida has recently been placed in this double bind. In 1981, HCFA approved a statewide Medicaid home and community-based waiver for an average monthly caseload of 6500 developmentally disabled persons. By virtue of the waiver, Florida has been able to dramatically limit the conversion of State institutional beds or the construction of new ICF/MR beds. Florida currently has the third lowest institutionalization rate of all States. Florida currently has a 99 percent occupancy rate in ICFs/MR and only 43 vacant beds. HCFA proposes to now reduce the waiver population to 43 which if implemented would require Florida to convert or construct thousands of new ICF/MR beds. Wouldn't the States with the most efficient and effective CON Programs and best diversion programs be penalized by having the smallest waiver populations?

Answer. At the outset, I would like to assure you that we have not suggested that the Florida MR waiver population be reduced to 43. We are working very closely with Florida officials to develop a waiver program which satisfies statutory and regulatory requirements. You should also be aware that HCFA did not approve a MR waiver program serving 6500 persons, but approved a program for roughly half that number of clients. Florida's request to expand its program beyond the 6500 figure represents a significant expansion of the program which we cannot accept. Under the most generous interpretation of the documentation supplied by Florida to date, we have been unable to establish that the large number of additional persons when Florida proposes to serve in this program would, but for such services, have been institutionalized in an ICF/MR.

Allow me to address your more general concern regarding the impact of bed closings and vacancy rate on the approvable size of a Medicaid home and community-based services waiver. Although the final rules governing this program require that a State provide information on the number of certified institutional beds by type as well as other information necessary for us to establish the validity of a State's assertions concerning diversion or deinstitutionalization, the rules do not limit waiver participation to the number of vacant beds. We have and will continue to include in our evaluation of State estimates of institutional utilization without waivers, those beds that have been closed as the result of the waiver as well as beds which the State can establish would be built, absent the waiver. In this regard, we regularly accept Certificates of Need (CON) and other health planning projections which are supported by documentation that bed development would really take place. We have taken this position to avoid penalizing States which have closed beds as a result of the waiver or have not constructed beds that would be needed and built, absent the waiver. On the other hand, we believe we must place an outer limit on waiver participation which relates to the number of persons whom the State would have actually been able to serve in Medicaid institutions absent the waiver. To do otherwise is to invite the use of Medicaid funding to finance services for clients who would not have become an obligation of the Medicaid program.

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Question. Have States shown, using HCFA's prescribed formula, that the waiver projects are cost-effective?

Answer. All States have projected cost-effectiveness using the formula prescribed in regulations as a condition for approval of their waivers. In terms of actual data received to date, most States have stayed within their original cost projections. However, the issue of cost-effectiveness is very complex. We have a major evaluation contract in place for this program which we believe will approach the issue of cost-effectiveness in a very thorough and scientific fashion. I would defer to the results of that study (expected late this year) for any generalization concerning the overall cost-effectiveness of the waiver program.

Questions Submitted by Senator Tom Harkin

Question. First, I want to ask straight out, when are we going to receive the revised Urban and Rural Wage Indices Report?

Answer. I am pleased to report that on March 29, 1985, Secretary Heckler submitted to the Congress the wage index study required by the Deficit Reduction Act. The report contains two alternative wage indexes developed from a survey of hospitals subject to the PPS. The survey was especially designed to address the principal limitation of the present index, its inability to measure regional variation in hospital part-time employment. The report contains no recommendation with respect to which index should be adopted. Before an index is adopted, we want to have the benefit of comments from the Congress, the hospital industry, and other interested parties.

Question. Will you be providing the Congress with all of the supporting data that you have collected and analyzed, including the results of the two or more audits that the Department has conducted on this data, with this report? (If not, why not?)

Answer. The wage index report required by section 2316(a) of the Deficit Reduction Act, submitted to Congress on March 29, 1985, contains two alternative wage indexes to PPS. The report also contains detailed explanations of the data base used to derive the indexes, the methods used to compute the indexes, and the estimated impact that would occur if the alternative indexes were implemented.

The data base itself is voluminous, since it contains survey reports and certifications from over 5,000 hospitals. However, should any member of Congress wish to examine this data, we will certainly make it available. My staff and I are also available to discuss the data and how it was used.

Question. The American Medical Association News of February 22, 1985, reported that this area wage index report will provide very favorable findings for rural hospitals in the country. According to this article, about half of the nation's rural

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hospitals will be getting more money per diagnosis related group (DRG) while the other half will be getting about the same amount per DRG as they now receive. Moreover, these findings have been validated by an HHS audit of 64 hospitals in the survey. Can you discuss these findings with me?

Answer. The report shows that both urban and rural hospitals would be affected by the revised indexes. While hospitals in some rural areas would realize increased payments from the implementation of a revised index, hospitals in other rural areas would experience decreases in their payment rates. We also estimate that the impact on urban hospitals similarly would be mixed.

Question. I understand that you have done a second audit of the findings of your initial area wage index report, in which you examined the data from 110 hospitals whose DRGs would change by 10 percent or more. Can you tell us what the findings from this second audit were? Will changes in the data from these 110 hospitals affect the area wage indices of the rest of the hospitals in the country?

Answer. Prior to the report's release, both the Health Care Financing Administration and the Department of Health and Human Services' Office of the Inspector General audited the survey reports of a sample of hospitals to assess their accuracy. As a result of these audits, the data used to compute the indexes was revised in a number of instances. These revisions resulted in the national average hourly wage changing by a few cents. Since each area's index reflects the relationship of that area's average hourly wage to the national average hourly wage, any change in the national figure can potentially alter an area's index. However, since the change in the national average was so small as a result of the audits, the impact on the area wage indexes was minimal.

Question. Suppose the wage index for a hospital went up by a few percentage points. What would be the increase in reimbursement that hospital would receive?

Answer. An increase in the wage index for a given area does not necessarily mean an increase in reimbursement for the hospitals in that area.

The wage index is used to calculate each hospital's Federal prospective payment by multiplying the average labor-related component of the standard urban/rural rate for each census division by the applicable area wage index value.

However, the labor-related component of each hospital's cost per discharge value used to develop those rates is standardized to remove the effects of differing hospital wage levels among the urban/rural areas. Standardization is achieved by dividing the labor-related portion of the cost per discharge values used to determine the rates by the wage index for the area in which the hospital is located. Therefore, in assessing the impact of changes in the wage index, it is necessary to examine both the percentage changes in the standardized rates that would apply under the new indexes, as well as the percentage change in any area's wage index.

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For any given area, if that area's wage index increases by a certain percentage, but the revised standardized rates applicable to that area decrease by a greater percentage, the hospitals in that area will experience reductions in their prospective payments. In fact, as the impact analysis included with the report shows, this result applies in a number of areas.

Question. Are you working now on a formula to make adjustments in reimbursement to hospitals which are found to have higher area wage indices? What would this formula look like? Are you contemplating a lump sum payment to that hospital or a phased-in reimbursement over time or some other method? Will this procedure for reimbursement be the same for every hospital?

Answer. Up to this point, we have devoted all of our resources to the development of alternative wage indexes which will resolve the full-time and part-time issue, and to the preparation of the report required by section 2316(a) of the Deficit Reduction Act. We have not yet formulated any recommendations on how recovery of overpayments or refund of underpayments should be made. We are at the initial stages of examining the methods that would be appropriate for implementing any new wage index retroactive to October 1, 1983, as the law requires.

Question. What about hospitals whose area wage indices go down? How will they be required to repay their overpayments: lump sum, overtime, or some other manner?

Answer. Let me emphasize that it is not our intention to disadvantage hospitals by an unfair collection procedure. Therefore, one of the options we are examining is a collection and refund procedure that would allow collections and refunds to proceed over a period of time.

Question. How much would a hold-harmless policy with respect to hospitals affected by the area wage index report cost? (i.e., if we did not require any hospital to repay the overpayment)

Answer. It is very difficult to determine what the cost of such a policy would be. We estimate that if the gross or adjusted HCFA wage index were adopted, the cost could approach $300 million.

However, it is necessary to point out that these figures reflect only the impact of changes in the wage index. In actual payment situations, factors such as the degree of teaching activity in individual hospitals, and individual hospital case-mixes, will act to increase or decrease these figures because of their multiplicative effects.

In any event, it should be noted that a hold-harmless policy as you describe would be very disadvantageous to the Medicare Trust Fund, since payouts would not be offset by any collection of overpayments.

Question. As further follow-up to this area wage index report, you are required to study and report to the Congress on proposed criteria under which future adjustments in Medicare

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prospective payments to hospitals could be made. This portion of the Deficit Reduction Act is critical to enable hospitals in the future to have some means to appeal their DRG levels. What are your thoughts on how this process will work? Are you preparing approaches to this issue now? When will this report be submitted to Congress?

Answer. Section 2316(c) of Public Law 98-369 requires the Department to conduct a study on the establishment of criteria for an adjustment to the wage index for those hospitals where the present measure may not accurately reflect the labor market serving the hospital. Because the technical accuracy of any new wage index which resolves the part-time employment problem will have a considerable bearing on the criteria which should be recognized for purposes of this adjustment, we believe the development of the criteria required under section 2316(c) of the law should be deferred until hospitals and the Congress have had an opportunity to react to the alternative wage indexes presented in the wage index report. While we are currently devoting our available resources to the development of an improved wage index, we intend to address the requirements of section 2316(c) as soon as practicable.

SUBCOMMITTEE RECESS

Senator PROXMIRE. The subcommittee will stand in recess until tomorrow, Thursday, March 28 at 9:30 a.m. here in room 116 of the Dirksen Building. At that time, we will hear testimony from the following in the Department of Health and Human Services: Human Development Services; Office of Community Services; Departmental Management, Salaries and Expenses; and Policy Research.

The subcommittee stands in recess.

[Whereupon, at 12:33 p.m., Wednesday, March 27, the subcommittee was recessed, to reconvene at 9:30 a.m., Thursday, March 28.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

THURSDAY, MARCH 28, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 9:37 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senators Weicker and Proxmire.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF HUMAN DEVELOPMENT SERVICES

OFFICE OF COMMUNITY SERVICES

STATEMENTS OF:
DORCAS R. HARDY, ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT SERVICES
HARVEY R. VIETH, DIRECTOR, OFFICE OF COMMUNITY SERVICES
ACCOMPANIED BY:
NORMAN GOLDSTEIN, DIRECTOR, OFFICE OF MANAGEMENT SERVICES
DENNIS P. WILLIAMS, ACTING DEPUTY ASSISTANT SECRETARY, BUDGET

PREPARED STATEMENT

Senator WEICKER. The subcommittee will come to order.

Today we will hear testimony concerning the appropriations under the Office of Human Development Services and the Office of Community Services, followed by testimony on departmental management activities.

We will begin with Dorcas Hardy, the Assistant Secretary for Human Development Services, and then hear from Dr. Harvey Vieth, Director of the Office of Community Services. If you would introduce your colleagues and proceed any way you deem.

Your statement will be placed in the record.

[The statement follows:]

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STATEMENT OF DORCAS R. HARDY

I am pleased to appear before you today to discuss the fiscal year 1986 budget request for programs administered by the Office of Human Development Services and the requests for rescissions and supplementals for fiscal year 1985.

For 1986, a total of $5,410,161,000 is requested to support a variety of social programs which serve children and youth and their families, the elderly, those who are developmentally disabled, and Native Americans. Of the total requested, $2,700,000,000 is requested for the Social Services Block Grant appropriation; $1,969,167,000 is requested for the Human Development Services appropriation; and $740,994,000 is requested for the Family Social Services appropriation. No funds are requested for the Work Incentive Program (WIN). With the exception of the WIN program, amounts requested for most Human Development Services programs are the levels provided by Congress for fiscal year 1985. This is consistent with overall Administration policies to freeze program support at 1985 levels. In order to futher reduce the deficit, we have requested reductions in discretionary areas which do not provide direct services.

With the exception of the Work Incentive Program, service levels for all programs supported in fiscal year 1985 will be maintained or increased to the extent possible through implementation of program and management initiatives.

A level of $2,700,000,000 is requested for the Social Services Block Grant to continue support for a variety of social services through the States. The amount requested represents the full authorization for this program in fiscal year 1986. Services which a State may choose to provide may include, but are not limited to: child and adult day care services,

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protective services, foster care, transportation, training, information and referral, counseling, delivery of meals, and health support. Although no funds are requested for the Community Services Block Grant, States may use Social Services Block Grant funds to support most of those activities previously carried out under the Community Services Block Grant for which authority also exists under the Social Services Block Grant.

A level of $1,969,167,000 is requested for the Human Development Services appropriation. This appropriation includes programs for children and youth and their families, the elderly, those who are developmentally disabled, and Native Americans.

For the Head Start program, $1,075,059,000 is requested to support comprehensive child development services to 448,250 preschool children and their families, the same number expected to be served in 1985.

For Child Abuse and Neglect programs, $22,000,000 is requested to improve and increase activities for the identification, prevention and treatment of child abuse and neglect. Of the amount requested, $12,000,000 will be awarded to States, and $10,000,000 will support discretionary activities, including $3,000,000 for the prevention and treatment of sexual abuse

For Runaway and Homeless youth programs, $23,250,000 is requested to support 275 centers expected to serve 80,000 youth and their families.

For the Administration on Aging, a level of $689,100,000 is requested. The request will provide a wide range of social and

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nutrition services to approximately 9 million elderly persons. Approximately 218 million meals will be served to over three million older persons.

For Developmental Disabilities programs a level of $73,000,000 is requested. The program will continue to support State systems which coordinate, monitor, and evaluate services provided to the developmentally disabled; to provide for systems of protection and advocacy of individual rights of persons who are developmentally disabled; to provide support for University Affiliated Facilities; and to increase private sector employment for developmentally disabled people.

For Native American programs, $27,300,000 is requested to promote social and economic self-sufficiency for American Indians, Alaska Natives and Native Hawaiians.

An amount of $59,458,000 is requested for Human Development Services Program Direction. These funds will provide effective and efficient management of all programs administered by the Office of Human Development Services.

A level of $740,994,000 is requested for the Family Social Services appropriation. The Administration will propose legislative changes in the Foster Care program that will improve State incentives to effect early reunification of children with their families or provide for other permanent placement of children. Funds requested will continue to provide assistance to States to strengthen the family unit, to reunify children with their families, or, where this is not possible, to find suitable adoptive homes for them. These funds will support the Child Welfare Services and Training programs, and the Foster Care and Adoption Assistance programs, Child Welfare Research and Demonstration, and Adoption opportunities.

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The Work Incentive Program is proposed for phase-out in 1985 because, as studies by the General Accounting Office have demonstrated, this program has not proven to be cost effective. Instead, legislation will be proposed which requires all States to phase in, over three years, requirements that all employable adult AFDC applicants participate in job search, and that all recipients participate in work activities.

In addition, Mr. Chairman, a supplemental request of $79,495,000 will enable us to meet current year estimates and allowable prior year claims under the Foster Care and Adoption Assistance programs. Of this amount $33,091,000 is proposed for transfer from other Health and Human Services accounts. Of the total requested, $34,883,000 will be used to pay prior year claims. Since States have two years to submit claims for reimbursement, annual program costs are difficult to estimate.

Of the $79,495,000 requested, $56,944,000 is requested for the Foster Care program. As you know, this is an open-ended entitlement program and we are required by law to meet all claims deemed allowable. We estimate that the additional amount requested will be sufficient to pay prior year claims that have been approved and to meet 1985 current law requirements.

The remaining $22,551,000 is requested for the Adoption Assistance program. Like the Foster Care program, the Adoption Assistance program is an open-ended entitlement program. This program is designed to facilitate the placement of children for whom permanent placement is difficult due to age, minority status, or the presence of handicapping conditions. The additional funds requested will enable us to pay the increasing number of allowable claims, as well as to meet prior year claims deemed allowable.

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We are also proposing rescissions in accordance with section 2901 of the Deficit Reduction Act of 1984. Of the total $1,730,000 proposed for rescission, $1,334,000 will come from Human Development Services, and $396,000 will come from Family Social Services. These rescissions will reduce amounts available for travel, consultant services, and printing and publications.

Thank you, Mr. Chairman. My colleagues and I will be happy to answer any questions you and the committee may have.

BIOGRAPHY OF DORCAS R. HARDY

POSITION	:	Assistant Secretary, Office of Human Development Services
BIRTHPLACE AND DATE	:	Newark, New Jersey, July 18, 1946
EDUCATION	:	B.A., Connecticut College, New London, Connecticut, 1968
	:	M.B.A., Pepperdine University, Los Angeles, California, 1976
	:	Executive Program in Health Policy and Financial Management, Harvard University, December, 1978
EXPERIENCE		
Present	:	Assistant Secretary, Office of Human Development Services
1974-1981	:	Associate Director, Center for Health Services Research, University of Southern California School of Medicine, Los Angeles, California
1974	:	Health Consultant, Urban Management Consultants, San Francisco, California
1973-1974	:	Assistant Secretary for Health, California Health and Welfare Agency, Sacramento, California
1971-1973	:	Executive Director of Health Services Industry Committee, Cost of Living Council, Washington, D.C.
1970-1971	:	Special Assistant to National Chairman and Director, White House Conference on Children and Youth, Washington, D.C.
1970	:	Legislative Research Assistant, Senator Clifford P. Case, Washington, D.C.

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INTRODUCTION OF ASSOCIATES

Ms. HARDY. Thank you.

I am accompanied by Norman Goldstein, Director, Office of Management Services, Dennis Williams from the Department's Office of Management and Budget and, as you noted, Dr. Vieth. I have some remarks to make as does Dr. Vieth.

BUDGET REQUEST

We are here to discuss a $5.4 billion budget for Human Development Services which will be used to support a variety of social service programs for children, youth, families, older Americans, persons who are developmentally disabled and native Americans. Though this is the 1986 budget request, I would like to take the opportunity to bring you up to date on a couple of areas that have been quite successful over the past year that I think merit your attention.

I am particularly pleased to talk about child abuse. It is a tragic problem and something we talked about at past hearings. It cuts across all social classes and communities. Private sector groups, such as the National Committee on Child Abuse Prevention and Neglect, have been instrumental in raising a real national consciousness and national awareness over the past decade. At the same time, there has been a lot of good support from private self-help groups, such as Parents Anonymous, which dramatically articulated this problem and provided parental support and assistance to communities across the country. We have seen States revise their laws and procedures for dealing with child abuse and make their systems more responsive to handling complaints expediently, as well as humanely. And I am convinced that much of the reported increase in child abuse cases stems from the great improvements made in State responsiveness to the problem that, unfortunately, has been with us for a long time but has been in the shadows.

As far as the Federal Government is concerned, we feel we have provided some significant leadership and national focus on the problem of child abuse. Funds for State grants have supported the development of numerous local services programs. Research and demonstration activities have led to working with parents, child care providers, State agencies, school districts, law enforcement agencies, and others to deal with the prevention of child abuse and neglect.

I would also like to bring to the committee's attention the significant progress we have made in moving children from foster care into permanent situations, whether it is an adoption or a return to biological parents. Many of these children are special-needs children who are older, are handicapped, or are minority children and are free for adoption but who historically have remained in foster care.

Federal adoption subsidies paid for about 1,400 children in 1982. In 1986, we estimate that over 18,000 children will benefit from the program. We believe that each of these children deserves a permanent family and a home, and adoption needs to be promoted as an alternative to long-term foster care.

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Another example of progress is a Presidential initiative for which our Department and my office has the lead. It concerns the employment of developmentally disabled persons. Last November, we made a commitment to place 25,000 developmentally disabled persons into permanent competitive jobs. That optimism and confidence was not particularly shared by everyone, but I am pleased to report that we have exceeded the placement rate of 25,000. We have pledges of 43,000 jobs. We expect we will meet and exceed 50,000 placements in 1985 and 75,000 placements in 1986.

A final example relates to the elderly and specifically to the progress we have made in the area of Alzheimer's disease throughout the country. We have provided support to groups that have been established in nearly all of our States to help families deal with Alzheimer's.

Returning to the specifics of our 1986 budget request, you will note in most instances the budget does reflect the administration's policies to freeze or level fund at the 1985 level. We believe that we can maintain or increase levels of service without additional funding. We believe this can be accomplished through continued implementation of program and management initiatives. One example is in the head start area where services will continue to be extended to more than the 448,000 children who we will serve this year.

Another example is in the Aging Program area where both the levels of service and number of meals is expected to increase over the 1985 levels. As I indicated earlier, we also plan to continue our initiative to employ developmentally disabled persons. We believe our budget request for 1986 represents a very carefully considered and balanced response to the needs of all of our vulnerable populations.

Thank you, Mr. Chairman. I will be glad to answer any questions after Dr. Vieth proceeds with the Office of Community Services.

PREPARED STATEMENT

Dr. Vieth, before you proceed, we will insert your statement in its entirety in the record at this point.

[The statement follows:]

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STATEMENT OF HARVEY R. VIETH

Mr. Chairman, Members of the Committee, thank you for the opportunity to appear before you today to discuss the Administration' fiscal year 1986 budget request for the Office of Community Services.

The President's request includes a proposal to repeal the Community Services Block Grant (CSBG) Act, administered by the Office of Community Services (OCS), and amend the Social Services Block Grant (SSBG) Act to clarify that States have the authority to use SSBG funds to support virtually all activities currently funded under the CSBG Act. The request includes $3.864 million for OCS to cover the salaries and expenses of 36 full-time equivalent positions to close out CSBG block grant and discretionary activities of prior years, and to support the operations of the Federal Task Force on Food and Shelter for the Homeless.

Before discussing the rationale for the repeal of the CSBG Act, I would like to note that current funding for the CSBG program -- $368 million -- represents only a fraction -- considerably less than one percent -- of the $65 billion the Administration is proposing be spent in fiscal year 1986 on programs for the poor. These programs, which include AFDC, food stamps, medicaid, supplemental

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security income, and others, constitute the basic "social safety net" for the poor and would not be affected by the repeal of the CSBG Act.

Repeal of the Community Services Block Grant Act

The proposal to repeal the CSBG Act is based on the fact that the CSBG is duplicative of other federal programs in three ways: (1) the States use CSBG for the kinds of activities which are supported from another federal block grant --the Social Services Block Grant; (2) most of the CSBG allocations to the States is used to cover the cost of administering other federal programs and is duplicative of the administrative overhead authorized for these programs and (3) that portion of CSBG funds which is reserved for the so-called "discretionary programs" administered directly by OCS duplicates funding authorities for identical programs operated by other federal agencies.

1. Duplication of Functions Between the CSBG and the Social Services Block Grant (SSBG).

The two block grants are essentially the same in terms of their statutory purposes, the kind of activities they support, and the type of clientele they serve. The stated purposes of the CSBG and the SSBG are (1) to break the cycle of poverty (in the case of the CSBG) and dependency (in the case of the SSBG) and (2) to provide a range of services to help offset the

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effects of poverty. The Department has also submitted a proposal to amend the SSBG Act to add the phrase "alleviate poverty" to the purposes section to further insure that funds continue to be targeted towards economic self-sufficiency when the CSBG is repealed.

To break the cycle of poverty is frequently cited as the primary goal of the CSBG --- a goal which it inherited from its predecessor programs operated by the Office of Economic Opportunity (OEO) and later by the Community Services Administration (CSA). However, there is no evidence that the anti-poverty activities conducted over the years by OEO, CSA, and currently by OCS, have had any significant impact on breaking the cycle of poverty. In reality, it is the second of the two purposes mentioned above -- to provide services to offset poverty -which has become dominant in the CSBG. The principal instrument for carrying out this purpose --- the network of some 860 community action agencies -- has become essentially a social services delivery system alongside other such systems.

The problem of duplication of social services delivery systems at the State and local level was noted by the Institute for Local Self-Government (ILSG) in its report on the CSBG in June 1982. The Institute commented: "The human services system in most States is a patchwork of categorical programs, block grant programs

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and combinations of the two. The way the system has developed over seventeen years has created problems of several programs providing the same services, clients that must receive basic services from as many as five or more different programs and certain needy populations that receive no service at all."

The same point was made in a proposal submitted to OCS by the National Governors' Association (NGA) in August 1983. According to the NGA: "Studies indicate that expenditures for human services comprise 51% of the Federal domestic budget and some 63% of aggregate state budgets. Yet, it is a misnomer to speak of a human services system. The enormous, costly effort to provide services to individuals is actually a patchwork of activities involving many different governmental agencies at the Federal, state and local level, as well as a wide array of private agencies and nonprofit corporations. No single governmental or private authority supervises or reviews this vast and complex process. As a result, there is enormous duplication of services and widespread inefficiency in the system, along with a failure to produce the results expected of the system. Thankfully there is a rapidly decreasing emphasis on single-purpose, categorical programs and increasing emphasis on flexible, multiple-purpose programs which can deal with human service needs in a more comprehensive way."

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The movement to consolidate social services delivery systems is well underway at the State level. According to the ILSG report, in 1982 sixteen States were sharing expert services among agencies, 14 States had multiple agencies doing joint outreach, and 12 States were sharing administrative costs among agencies. A similar finding appeared in a January 1982 report on the SSBG by the American Public Welfare Association (APWA). According to the APWA report: "Several States are considering increased coordination and integration of services at both the administrative and services delivery levels. At least one State, California, sees this as a positive effect of the block grant legislation. Kentucky and Massachusetts are looking at ways to eliminate duplication of services provided under Title XX (now the Social Services Block Grant) and under the Community Services Block Grant" (Parenthesis added).

As is the case at the State levels, the duplication of funding mechanisms, administrative staffs and reporting requirements at the Federal level creates inefficiencies and increases costs. In a period of soaring Federal deficits, this overlap is unacceptable. The Administration is proposing to amend the SSBG Act to allow states to use SSBG funds to support virtually all activities formerly funded under the CSBG. It is conceded that some of the activities now funded under the CSBG are not identical with those funded under the SSBG. But

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they all fall under the same category of "human services" or "social services" activities. Repeal of the CSBG would not only accelerate the trend toward consolidation of these services at the State and local levels, thus reducing administrative costs at all levels of government, but would also give the States greater latitude in developing a mix of services best suited to the unique economic and social needs of a particular State.

According to a report prepared by the National Governors' Association, the experience with block grant implementation "reinforced the thesis that policy planning and prioritization of needs and services can better be performed by those closer to the target populations and service areas." Currently, under the SSBG, States are able to exercise almost complete flexibility in program administration as well as program development and resource allocation. The CSBG, on the other hand, allows the States little flexibility to allocate funds in line with their differing needs and priorities, since they must pass 83 percent of CSBG funds through to grantees that existed in 1981. The repeal of the CSBG Act and the amendment to the SSBG Act would give the States additional flexibility in ranking priority needs across the board, and in selecting the best service providers to meet these needs at the lowest possible cost.

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The network of grantees that existed in 1981, and for whom most of the CSBG funds are now earmarked, includes (as noted above) some 860 community action agencies formerly funded by the Community Services Administration and earlier by the Office of Economic Opportunity. The proposal to repeal the CSBG Act and amend the SSBG Act has frequently been misread as a proposal to abolish this network. It is true that the $2.7 billion budget proposed for the SSBG in fiscal year 1986 -- although it is seven times the current funding level of the CSBG -- may not be able to support each and every one of the activities funded separately under the two block grants in fiscal year 1985. On the other hand, States could be expected to either drop low priority SSBG activities in order to fund former CSBG activities which they believe have greater utility or continue to support existing services with State, local and private resources. There is no reason why effective community action agencies cannot compete successfully for SSBG, State, local and private funds.

2. Duplication of Funding for Administrative Overhead

The principal reason the repeal of the CSBG Act should pose no real threat to the continued existence of effective community action agencies is found in the following statistic reported in a study conducted by the

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National Governors' Association, CSBG funds account, on average, for only 12 percent of total community action agency funding.* Nearly 86 percent of community action agencies' funding derives from other federal authorities, including the $2.1 billion Low Income Energy Assistance Program, the $1.075 billion Head Start program, and the Department of Energy's $153 million weatherization program. In addition, the community action agencies receive funds from a number of other federally-funded programs such as the Alcohol, Drug Abuse and Mental Health Services Block Grant, the Community Development Block Grant, the Job Training Partnership Act programs, ACTION's Foster Grandparents and Senior Companions programs, and the Administration on Aging's nutrition and other supportive services programs for the elderly (See Attachment #1).

Most of the CSBG funds passed through by the States to the CAAs are used to finance core staff and operating costs required to administer the federal programs listed above.* But all of these multi-million dollar Federal programs have in their budgets allowances for administrative overhead (staff, rent, heat, light, supplies, etc.) which collectively, and without the increment of

*Report on "First Year...of the CSBG" by the National Association for State Community Services Programs, dated February 18, 1983

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CSBG funds, should suffice, along with existing State and local funding , to (1) cover the cost of administering the above-mentioned programs and (2) maintain in existence those CAA's which have been performing effectively. In short, the CSBG is not only a redundant source of funds for administrative overhead, but is not vital to the continued existence of the CAA's.

That CSBG funds are not essential for administering the above progarms is further evidenced by the fact that a number of these programs, such as the Head Start program, frequently make use of providers other than community action agencies to deliver the same services at least as efficiently and sometimes at less cost, without the benefit of CSBG funds.

At least one state (Michigan) has begun to address the issue of duplication in administrative costs. In a newsletter published in September 1983 by the National Governors' Association, the following item appeared:

> "Another longstanding issue in the field of community action has been the amount of CSBG funding devoted to administration. Michigan felt the issue needed to be addressed because of concern that too high administrative costs were politically vulnerable. The FY'83 state plan restricts program administration to 25% thus eliminating the open-ended amount allowed in some states. Michigan views more aggressive CAA charging of administrative cost to other funding sources as an important positive outcome of the 25% requirement."

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*NCA/NASCAP Report, November 1984

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3. Duplication of Discretionary Programs

In addition to block grants to the States for social services, the CSBG Act authorizes a discretionary fund which represents approximately 9% of the total CSBG funding and which is used to support projects in such areas as community economic development, rural housing rehabilitation and repair, drinking water and waste water facilities improvement, assistance to migrant and seasonal farmworkers, and national youth sports. The funding breakdown for these programs in FY 1985 is as follows:

Urban and rural community economic development.....$19,920,000
Rural housing rehabilitation and repair, and technical assistance for rural drinking water and waste water facilities improvement.....$4,050,000
Assistance for migrant and seasonal farmworkers.....$3,035,000
National youth sports.....$6,130,000

The activities supported by these programs are the same, in kind, as those supported from other funding sources within the Departments of Housing and Urban Development, Agriculture, Labor and the Environmental Protection Agency (See Attachment #2). For example, community based organizations seeking funds for rural housing rehabilitation and repair projects are eligible for assistance from the HUD-administered Community Development Block Grant (CDBG) Program. In FY 1984, roughly $168 million in CDBG funds were used for housing rehabilitation

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and repair projects in rural areas. Funds for such projects are included in the Administration's FY 1986 request for $3.124 billion for the Community Development Block Grant.

With respect to drinking water and waste water facilities improvement, in FY 1984, OCS awarded 8 grants totalling $1.536 million to nonprofit organizations providing technical assistance to small, low-income rural communities seeking water and waste water construction funds from such agencies as the Environmental Protection Agency (EPA) and the Farmers Home Administration (FmHA). The technical assistance furnished under the OCS grants duplicates that already available elsewhere and in this period of federal budget stress should not be continued. In its budget request for FY 1986, the Administration is asking for $117 million for water and waste water treatment construction grants for rural communities. Of this amount, $25 million is earmarked for FmHA and $92 million for EPA. FmHA operates a network of nearly 1800 county offices and 290 district offices which offer technical advice and pre-application assistance to any rural community seeking help in improving their water and waste water facilities. Grant awards cover the costs of feasibility studies, engineering designs, legal fees, land acquisition fees, etc. Similarly, EPA funds 2000 state agency employees at the local level who provide pre-application and other types of technical assistance

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to urban and rural communities, (including low-income communities) with potable water and waste water problems.

Similar duplication is found in funding authorities for economic development projects. In FY 1984, $360 million in CDBG funds were expended for economic development projects throughout the country that were no different in kind from those currently funded by the CSBG.

In addition, the Department of Labor is requesting, for FY 1986, $60 million which can be used by private and public organizations to provide employment and training services for migrant and seasonal farmworkers.

We will continue to explore the possibility of expanding private sector involvement in the national youth sports programs.

In sum, the duplication of administrative staffs and federal monitoring and auditing created by the discretionary authority of the CSBG Act is expensive and unnecessary and constitutes another reason for repealing this Act. This would be true even if there were no federal deficit problem.

OCS Closeout

Finally, the fiscal year 1986 budget for the Office of Community Services requests $3,864,000 for Federal Administration. This includes $3,539,000 for benefits to former employees and salaries and expenses for 30 FTEs to oversee

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an orderly closeout of OCS functions as well as $325,000 for 6 FTEs to coordinate the Federal Task Force on Food and Shelter for the Homeless. This Task Force will be coordinated by another agency designated by the Secretary after OCS closeout.

Task Force on Food and Shelter for the Homeless

The role of the Task Force on Food and Shelter for the Homeless, which was created by the Secretary in October 1983, is fourfold:

1. To identify impediments to participation by the homeless in existing grant and entitlement programs for low-income persons, and to coordinate a federal effort to increase the use of these programs by the homeless.

2. To identify, and assist in making available to the homeless and organizations serving the homeless, surplus buildings, equipment, supplies and foodstuffs within the control of the various federal agencies.

3. In cooperation with the Committee for Food and Shelter Inc., to serve as a broker between federal agencies on the one hand, and State and local governments and the private sector on the other, in order to fully achieve the two goals stated above.

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4. To gather and disseminate practical information useful to local soup kitchen and shelter operators.

The Task Force has negotiated ten agreements with federal agencies to support local food and shelter operations. These include agreements with (1) HUD & USDA (FmHA) for single-family homes in their inventory to be used as shelters, (2) DOD for the renovation and lease of DOD facilities for use as shelters, and for the donation of non-marketable commissary foodstuffs to foodbanks, and (3) GSA for the lease of vacant federal buildings to be used as shelters and for the donation of surplus federal equipment to foodbank and shelter operators.

The efforts of the Task Force have resulted, among other things, in GSA-controlled buildings being made available for use as shelters in Seattle and Washington, D. C. and for use as food-storage facilities at two other locations. In addition, DOD-controlled buildings are being used as shelters at Kirtland Air Force Base in Albuquerque, New Mexico, Walter Reed Army Hospital Annex in Silver Spring, Maryland, a naval air station at Corpus Christi, Texas, a Naval reserve center at Lawrence, Massachusetts, a Naval reserve center in Philadelphia, Pennsylvania, a former Army finance center in Denver, Colorado and at Camp Parks Air Force Base in Alameda County California.

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The Task Force also played a key role in coordinating the efforts of the city government and private charities in Memphis, Tennessee to make available ten single-family units in the HUD-held inventory for use by homeless families. To date, the project has served 78 families and has been extended for a second year.

The Task Force has also been instrumental in raising the consciousness of federal agencies toward the plight of the homeless, thus resulting in a better targeting of programs to this fragile population.

Thank you, Mr. Chairman. This concludes my statement and I shall be happy to answer any questions you or the other members of the Committee may have at at this time.

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Attachment #1

OTHER SOURCES OF FEDERAL FUNDING FOR CSBG SERVICE PROVIDERS
(In FY 1982, $ 2.3 billion or 86% of the total CAA budget was derived from these other sources)

FEDERAL PROGRAM	TOTAL DOLLARS REQUESTED FOR '86	DEGREE OF CAA's INVOLVEMENT AS SERVICE PROVIDERS	ADMINISTRATIVE COST ALLOWANCE (% OF APPROPRIATION)
Low Income Energy Home Assistance Program (HHS)	$2.1 billion	Extensive	Up to 10%
Head Start Program (HHS)	$1.075 billion	55% of Head Start grantees are CAAs; 39% of Head Start operating programs are delivered by CAAs.	Up to 15%
Social Services Block Grant (HHS)	$2.7 billion	Unknown	No Limit
Alcohol, Drug Abuse and Mental Health Block Grant (HHS)	$490 million	Around 25% of ADAMHA programs use CAA's to deliver their services.	Up to 10%
Weatherization (DOE)	$152 million	Around 85% of weatherization services are provided by CAA's.	10% (5% for state administration and 5% for local provide
Community Development Block Grant (HUD)	$3.1 billion	Extensive	20 %
Job Training Partnership Act Block Grant (DOL)	$2.8 billion	Extensive	Up to 30%
Foster Grandparents Program (ACTION)	$55.7 million	Around 25% of these programs use CAA's.	Up to 10%

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OTHER SOURCES OF FEDERAL FUNDING FOR CSBG SERVICE PROVIDERS

(In FY 1982, $ 2.3 billion or 86% of the total CAA budget was derived from these other sources)

FEDERAL PROGRAM	TOTAL DOLLARS REQUESTED FOR '86	DEGREE OF CAA's INVOLVEMENT AS SERVICE PROVIDERS	ADMINISTRATIVE COST ALLOWANCE (% OF APPROPRIATION)
Senior Companion Program (ACTION)	$17 million	Around 25% of these programs use CAA's.	Up to 10%
Nutrition and Other Supportive Services for the Elderly (HHS/AOA)	$669 million	Extensive	Up to the greater of 5% of a state's allocation or $300,000

Note: This list is not exhaustive.

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Attachment #2

DUPLICATIVE FUNDING FOR DISCRETIONARY PROGRAMS

ACTIVITY	AGENCY	FUNDING
Rural Housing Rehabilitation and Repair	HUD (CDBG)	$168 million (FY 1984)
	OCS	$2.3 million (FY 1984)
Economic Development	HUD (CDBG)	$360 million (FY 1984)
	OCS	$19.9 million (FY 1985)
Assistance to Migrant and Seasonal Farmworkers	DOL	$60 million (FY'86 request)
	OCS	$3 million (FY'85)
Technical Assistance for Water/Waste Water Projects	EPA	Funding for 2000 field staff to provide advice and assistance
	FmHA	Funding for 1800 county and 290 district offices to provide advice and assistance
	OCS	$1.536 million for staff to provide advice and assistance

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Biography of Harvey R. Vieth

Position: Director, Office of Community Services
Department of Health and Human Services

Previous Positions: El Paso County Commissioner
Dentist

Military: Lieutenant, United States Navy - 1961 to 1963

Community Activities and Clubs:

* Member, Colorado Springs, Chamber of Commerce
* Grand Knight, Knights of Columbus, Colorado Springs Chapter - 1966
* Kiwanis International
* Board of Directors, Family Counseling Service, Colorado Springs
* Trustee, Knights of Columbus, Colorado Springs - 1967
* Member, Colorado State Board of Health (appointed by Governor) 1968
* Board Member, Memorial Hospital - (development of New Hospital facility) - 1970
* Staff Member, St. Francis Hospital - 1970
* Member, Colorado Board of Dental Examiners, (appointed by Governor) - 1972
* President of the Audubon P.T.A. - 1974
* Senior Chamber of Commerce Liaison Committee - 1975
* Fundraiser for the Poor Children of Guadalupe, Colorado Springs

Political Activities:

* National Delegate to the 1972 National Republican Convention in Miami
* Member of the Credentials Committee to the National Convention
* El Paso County Republican Party, County Chairman - 1973 and 1974
* Chairman for "Reagan for President", El Paso County - 1976
* National Delegate to the 1976 National Republican Convention in Kansas City
* Elected El Paso County Commissioner - 1980

Dental Organizations:

* Colorado Springs Dental Society
* American Dental Association
* American Association of Dental Examiners
* Central Regional Testing Service
* Colorado Board of Dental Examiners
* PSI OMEGA Dental Fraternity
* Blue Key Honor Fraternity (standing)
* Intermountain Association for Post Graduate Dentistry - (president) - 1967
* Honorary Degree from the Colorado University Dental School - 1977
* Dental Consultant for the Springs Village Nursing Home - 1977

Education:

1953 : Graduated - Ripon High School; Ripon, Wisconsin
1953-1954: Marquette University; Milwaukee, Wisconsin
1954-1957: Loyola University; Chicago, Illinois
1957 : B. S. - Major: Philosophy - Minor: Biology
1961 : D.D.S.

Personal Data: Wife: Sharon
Children: Laura, Robert, Julie, Thomas, Peter

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REPEAL OF COMMUNITY SERVICES BLOCK GRANT ACT

Mr. VIETH. Thank you, Mr. Chairman, for the opportunity to appear today and discuss the administration's fiscal 1986 request for the Office of Community Services.

The President's request includes a proposal to repeal the Community Services Block Grant Act, administered by the Office of Community Services, and amend the Social Services Block Grant Act to clarify that States have the authority to use SSBG funds to support virtually all activities currently funded under the SSBG Act.

The proposal to repeal the act is based on the fact that it is duplicative of other Federal programs in three ways: first the States use CSBG for the kinds of activities which are supported from another Federal block grant—the social services block grant; second most of the CSBG allocations to the States is used to cover the cost of administering other Federal programs and is duplicative of the administrative overhead authorized for these programs; and third, that portion of CSBG funds which is reserved for the so-called discretionary programs administered directly by OCS duplicates funding authorities for identical programs operated by other Federal agencies.

DUPLICATION OF FUNCTIONS BETWEEN THE CSBG AND THE SSBG

The two block grants are essentially the same in terms of their statutory purposes, the kind of activities they support, and the type of clientele they serve. The stated purposes of the CSBG and the SSBG are to break the cycle of poverty, in the case of the CSBG, and dependency, in the case of the SSBG, and, second, to provide a range of services to help offset the effects of poverty.

The duplication of funding mechanisms, administrative staffs, and reporting requirements at the Federal level creates inefficiencies and increases costs. The administration is proposing to amend the SSBG Act to allow States to use SSBG funds to support virtually all activities formerly funded under the CSBG. It is conceded that some of the activities now funded under the CSBG are not identical with those funded under the SSBG. But they all fall under the same category of human services or social services activities.

Incidentally, a proposal to repeal the act has frequently been misread as a proposal to abolish the community action agencies. With the new language, States could be expected to either drop low priority SSBG activities in order to fund former CSBG activities which they believe have a greater utility or continue to support the existing services with State, local, and private resources. There is no reason why effective community action agencies cannot compete successfully for SSBG funds.

DUPLICATION OF FUNDING FOR ADMINISTRATIVE OVERHEAD

CSBG funds issued to the States are used to support social service activities for the poor conducted by 1,070 community based organizations, including a network of 861 community action agencies. These

funds account on the average for only 12 percent of the total community action agency funding. Nearly 86 percent of the funding is derived from other Federal funding authorities. Most of the funds passed through by the States to the community action agencies is used to finance core staff and operating costs required to administer programs supported under these other Federal funding authorities. But each of these multimillion dollar programs have in their budgets allowances for administrative overhead which collectively should suffice to cover the costs of administering these programs and maintain in existence those community action agencies who have been performing effectively.

DUPLICATION OF DISCRETIONARY PROGRAMS

In addition to the block grants to the States for social services the CSBG Act authorizes a discretionary fund which represents approximately 9 percent of the total funding and which is used to support projects in the area of economic development, rural housing, rehabilitation and repair, drinking water and waste water facilities improvement, assistance to migrant and seasonal farm workers, and national youth sports.

The activities supported by these programs are the same, in kind, as those supported from other funding sources within HUD, Agriculture, Labor, and EPA.

The duplication of administrative staffs, Federal monitoring and auditing created by the discretionary authority of the CSBG Act is expensive and unnecessary and constitutes another reason for repealing the act.

Finally, OCS closeout. The fiscal year 1986 budget for the Office of Community Services request is $3.8 million for Federal administration. This includes money for benefits to former employees, salaries and expenses for 36 FTE's to oversee an orderly closeout of OCS functions and also funds to coordinate activities of the Federal task force on food and shelter for the homeless.

Thank you, Mr. Chairman.

This concludes my statement. I shall be happy to answer any questions you may have.

ABOLISHING WORK INCENTIVE PROGRAM

Senator WEICKER. According to your budget justification, page 200, the Work Incentive Program placed 38 percent more people in jobs in 1984 than 1983. This is accomplished by no increase in funding. Why do you want to abolish a program that was improving so dramatically, now annually places 350,000 individuals in unsubsidized employment?

Ms. HARDY. Mr. Chairman, our proposal that will be coming to you shortly is going to be a legislative proposal that combines the best efforts of several of the programs that have to do with work and work for those on welfare. We think that by combining those we can have a more successful effort.

Senator WEICKER. This is an appropriations committee; this is not a legislative committee. I have to go through this every year. This is not a legislative committee. Who prepares the budgets for your office?

Ms. HARDY. It's a collective effort.

Senator WEICKER. Collective effort. Don't you think from the point of view of budgetary practice that we should have before us the figures as it now stands on the books? Don't you think that is conservative budgeting, conservative fiscal practice in that sense? The way the law is written, in other words, that is what we should have before us. I don't know that there is going to be any legislation. If it happens, it happens. Then we come after that. But I don't accept that as an answer.

Ms. HARDY. We are——

Senator WEICKER [interposing]. Your answer is you want to eliminate the program?

Ms. HARDY. Correct, and we have proposed zero funding.

Senator WEICKER. It has nothing to do with my job here. You want to eliminate the program. It's a successful program, placing people in the private sector; you want to eliminate it?

Ms. HARDY. We do not see that it is as successful as you indicate.

Senator WEICKER. I am referring to your statement.

Ms. HARDY. Yes, sir.

Senator WEICKER. Thirty-eight percent is pretty good.

Ms. HARDY. Some of those figures are better than they have been in the past.

We also show that it does not make a significant amount of difference for individuals who are either placed or retained in jobs whether or not they have any kind of social support services.

Senator WEICKER. Your budget justification says one thing, and the bottom line of what you are requesting says another.

SUPPLEMENTAL REQUEST FOR FOSTER CARE AND ADOPTION ASSISTANCE

You have submitted a supplemental request for $79,495,000 to cover entitlement costs under foster care and adoption assistance. Yet you are only asking $46,404,000 in new budget authority, and proposing to transfer $33,091,000 from other programs.

It is my understanding, am I not correct, that Congress has repeatedly refused to go along?

Ms. HARDY. Yes; I believe that's correct.

Senator WEICKER. Wouldn't your proposed transfer eliminate appropriations for certain health projects of high priority to the Congress such as the Oregon Medical School and the University of Hawaii?

Ms. HARDY. Yes, sir.

Senator WEICKER. Why didn't you request rescissions for those specific activities you don't want to fund?

Ms. HARDY. Mr. Williams?

Mr. WILLIAMS. We chose to simply request a reappropriation of the money from one purpose to the other. One could have rescinded the money——

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Senator WEICKER. It is a little more direct.

Mr. WILLIAMS. If you rescind, it would require two actions—rescission and then supplemental appropriation. In this case, you can do both in one action. We are very clear about what the sources of funds would be and where they would be reappropriated to. It can be accomplished in one action rather than two separate actions.

HEAD START FUNDING FREEZE

Senator WEICKER. You are proposing a funding freeze for Head Start at $1,075,059,000. How do you expect to avoid cutbacks in the number of children being served since obviously you have an inflation factor involved?

Ms. HARDY. We have had experience of level funding as well as expanding Head Start over the last 4 years, and in the 2 years where we level funded Head Start, we were able to increase the number of children served. There are some dollar carryover balances throughout the system. Head Start is getting a significant increase this year that will support programs that start in September 1985, the end of this fiscal year. I think the program will continue to grow.

Senator WEICKER. Isn't it true that less than 20 percent of the eligible children now receive Head Start services?

Ms. HARDY. Yes, sir.

Senator WEICKER. There is a big community to be served out there, isn't there?

Ms. HARDY. And we have significantly expanded the funding for Head Start over the past 5 years, by about 20 percent.

PROTECTION AND ADVOCACY SYSTEMS

Senator WEICKER. As you are aware, the protection and advocacy systems are designed to protect and advocate for the rights of developmentally disabled persons.

With hundreds of thousands of mentally retarded and mentally ill persons living in institutions, and abuse and neglect being serious problem there, how can you recommend flat funding for this program?

Ms. HARDY. We believe the protection and advocacy systems are doing a good job currently. Consistent with the administration policy, recommend level funding and believe that they would continue those excellent services.

Senator WEICKER. Is it not true, Madam Secretary, that you proposed a cut of $5.3 million in protection and advocacy funds that was added back by the Department?

Ms. HARDY. I don't recall that, although there was probably some discussion looking at our whole budget. We had back-and-forth discussions.

Senator WEICKER. I have your request, which I received, the request you made to HHS is for $8.4 million and your request to OMB was $15 million, and the President's budget came down on $13.75 million, right? That is the table I have in front of me.

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Ms. HARDY. The $8.4 million, Mr. Chairman, would have been a return to 1984 authority and I requested level funding for 1985. I would be pleased to look at the papers that you have.

Senator WEICKER. The 1985 level was $13.75 million, the same level of funding that was in the President's budget.

Ms. HARDY. No, sir; the $13.75 million was the increased amount appropriated by the Congress.

Senator WEICKER. Your request was for $8.4 million.

Ms. HARDY. Well, I would like to know whether those are my papers or not.

Mr. WILLIAMS. Mr. Chairman, I think one thing to understand in the budget process, when the Office of Human Development Services estimates their budget to us, like other operating divisions and departments, in June of each year, they submit it under certain guidelines provided by the Department, certain guidance. One of the levels of guidance in the development of the 1986 budget at that stage of the process was that their requests in general be established at about the levels assumed in the 1985 President's budget, the budget year before.

Senator WEICKER. That is $13.75 million?

Ms. HARDY. No, Mr. Chairman; you had not made your decisions yet. In other words, we level funded in our first request—that was very early on—then our first submission in June was based on level funding of the year before. When the Congress added more money in the 1985 budget, we went back and level funded 1986 at the 1985 appropriated level.

Senator WEICKER. One hundred eighty thousand mentally retarded and approximately two hundred fourteen thousand mentally ill persons live in institutions. This is their only chance to make sure they have a voice. I think that kind of a request is hardly indicative of an advocacy role as far as you are concerned. At least they are supposed to be under your protection.

Let's go ahead and try and cut your staff and let you talk for yourself.

Senator Proxmire, go ahead.

PRENATAL CARE FOR LOW-INCOME WOMEN

Senator PROXMIRE. Secretary Hardy, earlier this month I met with the Wisconsin Primary Health Care Association. One of the issues we discussed was the difficulty of providing prenatal care to low-income women. As I am sure you know, a recent study by the National Institute of Medicine indicated that it is much cheaper to prevent low birth weight babies by providing good prenatal care than it is to care for those babies after they are born.

Unfortunately there are a number of reasons why pregnant low-income women are not receiving prenatal care. For example, the Milwaukee Department of Social Services mistakenly told a number of prospective clients that they were not eligible for benefits until their seventh month of pregnancy, although this was not the case.

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Is your office making any attempt to clarify the circumstances under which prenatal care can be provided to low-income women so that this kind of confusion does not arise?

Ms. HARDY. I was not aware of the confusion, Senator Proxmire. I will be glad to look into that and report back to you.

Senator PROXMIRE. The staff has suggested to me that there should be national guidelines that are as clear as possible as well as some procedure to insure that people understand them.

Ms. HARDY. We will follow up on that, sir.

Senator PROXMIRE. One group of women that are not receiving adequate prenatal care are undocumented aliens. Often these aliens will not risk identification through an application for prenatal care. This is a serious problem in Milwaukee. Of 182 low-income pregnant women identified in a recent time period, 55 fit this category. Of course, if they have low birth weight children because of a lack of prenatal care, those children will be entitled to the best of care as U.S. citizens.

Are you looking at ways to deal with this problem?

Ms. HARDY. We have not been involved in that particular issue.

Senator WEICKER. Who would be involved?

Ms. HARDY. The Office of the Assistant Secretary of Health out of the National Insitutes of Health and the Health Resources Services Administration; the clinical health side of HHS, but I am assuming you are saying the entry point for many of these people is through the social services system and there needs to be some clarification to that. We do communicate with the States, as they are dealing with the social services block grants, and we certainly can bring this to their attention.

Senator PROXMIRE. Of course, these are people who are afraid to report because they are aliens. Do you want to follow up, Tom?

Mr. VAN DER VOORT. As you say, the point of entry is the social service worker. These pregnant women are afraid to come in because they are going to be identified as aliens. Consequently they don't get prenatal services, and if they don't get the services, they will have low birth weight babies. This is a very sensitive area where a good deal could be done.

Senator PROXMIRE. Let me ask you about another group of women that may not receive adequate prenatal care—unwed mothers who refuse to divulge the identity of the father. How can we make sure these people are helped?

Ms. HARDY. They have the right of access to any of these services if the State deems them eligible. I don't know if I really have a specific solution as to exactly how to help them individually. If they are part of that social services network, they are certainly welcome to those services if they are eligible.

Senator PROXMIRE. I suppose the problem is a difficult one because they don't come forward and divulge the identity of the father. I suppose it is a matter for the community——

Ms. HARDY [interposing]. And the child support enforcement system.

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Senator PROXMIRE. The latest figures indicate Milwaukee County alone had 182 women eligible for prenatal care and 14 were misinformed about their eligibility for Medicaid. In another county an unmarried and pregnant woman was denied Medicaid because she would not divulge the name of the father. Does that make any sense? After all, the child is likely to be born, and a low birth weight baby would be a much more costly burden. It seems to me the fact the woman won't divulge the name of the father shouldn't prevent the Government from providing obviously desirable prenatal care that would save money in the long run as well as be an act of compassion.

Ms. HARDY. I can look into that more deeply. I think that has to do with some of the paternity determinations in the Office of Child Support Enforcement and the eligibility questions under AFDC.

Senator PROXMIRE. At any rate, it is a question of trying to be——

Ms. HARDY [interposing]. Also just from a hardheaded, perhaps coldhearted, standpoint of saving the Federal Government money.

Senator PROXMIRE. That's right. Providing prenatal care would do both things.

COST OF EDUCATION CUTS

Secretary Hardy, the chairman has already questioned you to some extent regarding the Head Start Program and I want to question you further. On page 47 of your justifications you seem to indicate that you are cutting the per-child cost of education in the Head Start Program by increasing the size of head start classes.

Last year you estimated the cost per child would be $2,448 in fiscal year 1985. This year you have revised the estimate downward to $2,335 per child. You also estimated last year that 429,000 children would be served by 23,900 classes. You now estimate that more children—448,000—will be educated in fewer classes—22,000. As I calculate it, that means an increase in children per class from 18 to 20.

Do you attempt to follow any rough guidelines to insure that there are not too many children in a head start class or is this strictly up to the grant recipient?

Ms. HARDY. No, sir; we do work closely with the grantees in terms of number of children per classroom and they do vary around the country. They range from 14 to 18 children in a class; 19 to 20 children in the class, it depends on the type of class; it depends on what kind of Head Start Program is in this particular grant area.

[CLERK'S NOTE.—Following the hearing the Department informed the committee that the size of Head Start classes ranged from 8 or 10 to over 20.]

Senator PROXMIRE. On page 46 of your justifications for fiscal year 1986 it indicates you have a maximum of 18 per class, as you just told me, but 20 on the average per class.

Ms. HARDY. That is 20, it could be in some cases a little higher. That is also enrolled children generally as opposed to attending children as well. There is generally not that many children in the class, but we are

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concerned that we retain that quality of care, the quality of that whole Head Start Program.

Senator PROXMIRE. It seems clear there has been an increase in the number of children per class which would normally result in less attention per child, right?

Ms. HARDY. Our figures do indicate that, yes.

Senator PROXMIRE. Does that concern you?

Ms. HARDY. I think we have been able to retain and even improve the quality of Head Start throughout the country.

Senator PROXMIRE. How can you do that when you have bigger classes? These are little children. It is not as if you are dealing with college students.

Ms. HARDY. We are also talking about enrolled children as well as children in that class every day, attending children. We have different types of Head Start programs—home based, a mix with head start center-based programs.

Senator PROXMIRE. Does that suggest fewer children than are enrolled are actually showing up?

Ms. HARDY. There are fewer children attending that are enrolled on a daily basis.

Senator PROXMIRE. Is the absence of children who are enrolled increasing?

Ms. HARDY. No; we think it is about the same.

Senator PROXMIRE. Then the number of children in attendance per class is increasing. Last year, you estimated there would be 80,825 paid staff in the Head Start Program in 1985. This year's justifications have revised that figure downward to 76,300 but show a substantial increase in the number of volunteers.

How do you think the reduction in paid staff will affect the Head Start Program?

Ms. HARDY. We think that the figures that are shown there will still retain the quality of the Head Start Program and will provide services to expand the number of children.

Senator PROXMIRE. I hope you are right. It just seems logical that with fewer teachers and more students, the quality of instruction would tend to decline, even though I am sure these teachers are making a strong effort.

Ms. HARDY. We also, I believe, Senator, have an adjustment—someone has just given me a note. There is a wrong figure in there. We would like to clarify it for you.

[CLERK'S NOTE.—After the hearing, Secretary Hardy submitted the following statement: "There is not a real decrease in the number of teachers. You are comparing last year's 1985 estimate, before we had completed our 1984 activity, with this year's estimate of the numbers of teachers that will be supported with the 1985 appropriation. This is still an estimate."]

Mr. GOLDSTEIN. The number of teachers is actually remaining the same for both years.

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Senator PROXMIRE. Even if that is the case, you still have projected a decline in paid staff from 80,000 to 76,300.

I note that you fell short of your original 1985 nutrition services goals under the Older Americans Act. Last year you estimated you would be able to deliver a total of 218.7 million meals in 1985. This year, that figure has been revised downward to 214.8 million meals despite a budget addon of about $21 million. Can you tell us why this is? While you are looking at those figures, I might just say the man on your right is a good man. He is from Wisconsin—born there, brought up there, and educated there. That is why he's so smart. [Laughter.]

Ms. HARDY. Senator, my figures do not jibe with what you have just said. We intend on serving 215 million meals in 1985 and 218 million meals in 1986.

Senator PROXMIRE. Originally you projected 218,663,000 meals would be served in 1985. This year you indicate only 214,819,000 meals will be served in 1985. That is a drop of nearly 4 million meals. Why is there a drop even though we increased your funding?

Ms. HARDY. There should not have been a decrease, Senator, and I do not know the answer to that. We don't agree on the figures.

Senator PROXMIRE. Can you give us the information for the record?

Ms. HARDY. Yes.

[CLERK'S NOTE.—After the hearing, Secretary Hardy submitted the following statement: "Again, we are dealing with estimates made a year apart for service levels that have not yet been provided. We now have information from the 1984 year that was not available a year ago and, therefore, have updated our estimates for 1985. We will not have final 1985 figures for almost another year, but the revised estimate is still an increase over the number of meals served in 1984."]

Senator WEICKER. I think these questions are right on the mark. I am just sitting here. I am the one who is supposed to be the liberal, spending peoples' money, all the rest of this. I listen to this business—it is the enrollees, not the attendees. I am a conservative when it comes to budgeting. If you are going to budget properly, you base it on the number of kids enrolled and you assume all those kids are going to be there; isn't that the way you budget?

Senator PROXMIRE. Exactly.

Senator WEICKER. Not these fellows.

GRANT REVIEW PROCESS

Senator PROXMIRE. Secretary Hardy, last year, we discussed the grant review process at your agency. I focused on the fact that you often passed over projects that received high scores from your review panels in favor of projects that ranked much lower.

One problem I did not discuss but which was touched upon by your inspector general was that often there was no documentation in the file as to why a high-scoring proposal had been rejected. In fact, in a response to the inspector general dated March 5, 1984, you stated, and I quote: "We have also developed new approaches to assure adequate documentation of all decisions."

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Despite this assurance a GAO review of the records of fiscal year 1984 award decisions in 5 of 13 priority areas revealed that in 20 out of 52 cases involving denials of awards for applications with scores equal to or greater than funded applications, the only justification given for the denial was the word "no." Do you consider this to be adequate documentation?

Ms. HARDY. No; and I believe we have corrected that and that we have a good process going on at this time.

Senator PROXMIRE. This funding was made in October 1984.

Mr. GOLDSTEIN. Senator, if I may, the word "no" that was alluded to there was a reflection of the end result. There was a lot of discussion relative to each of these proposals as to whether they would be accepted or not accepted.

Senator PROXMIRE. Could I just interrupt, Mr. Goldstein, to say that we are talking about documentation. Why shouldn't there be documentation in the files? I am not talking about——

Mr. GOLDSTEIN. Your point is well taken and, in fact, we have modified our procedures as a result of the inspector general's report. Our current procedures provide for a much more thorough documentation. I only wish to assure you that the basis upon which those decisions were made was a very thoughtful one, even though there may be some omissions in the context of the Department of the——

Senator PROXMIRE. But that documentation had not shown up as of October 1984, a fairly recent date.

Mr. GOLDSTEIN. I am saying the documentation for the fiscal year 1985 process has been substantially improved.

Senator PROXMIRE. Thank you, Mr. Chairman.

Senator WEICKER. Thank you for those excellent questions, Senator Proxmire.

UNIVERSITY AFFILIATED FACILITIES PROGRAM

The University Affiliated Facilities Program offers a variety of training activities for individuals working with developmentally disabled persons.

Can you tell me when the UAF satellite proposal of the University of Connecticut will be approved? I understand that substantial non-Federal resources will be attracted by the UAF designation but that delays will cause these resources to diminish. For example, $25,000 State mental retardation funds intended for the UAF has gone elsewhere because of the delay.

When is the project going to be approved?

Ms. HARDY. The three satellite proposals are due into the office in the middle of April and will be reviewed at the end of April for funding soon thereafter for successful projects.

Senator WEICKER. What are we talking about as to the bottom line on time?

Ms. HARDY. I would hope that it would be early summer.

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ELDERLY NUTRITION PROGRAM FREEZE

Senator WEICKER. Last fall, Congress raised the authorization for the Elderly Nutrition Program to $448.5 million; yet you are proposing to freeze funding at the fiscal 1985 level of $403.9 million.

Do you feel an increased appropriation of $44.6 million could be effectively used in fiscal 1986?

Ms. HARDY. Our proposal is to level fund the nutrition prog am and continue to increase the number of meals that we serve next year.

DAILY NUTRITIOUS MEALS FOR THE ELDERLY

Senator WEICKER. How many more elderly people will receive daily nutritious meals with these extra funds? Can you give me the answer to that?

Ms. HARDY. We estimate that about 3 million individuals received them this year. Three million more meals, sir.

Senator WEICKER. Three million more?

Ms. HARDY. Yes.

Senator WEICKER. In view of the rapidly increasing elderly population, many of whom cannot afford the voluntary contributions for these meals, don't we risk falling further behind if we don't expand Federal support for the program?

Ms. HARDY. We are serving more meals and our contributions are continuing to increase.

Senator WEICKER. Again, here did you not ask for a cut of $20 million? HHS overruled this and you asked OMB for a $20 million increase?

Ms. HARDY. That is the same discussion we had earlier, sir, about the timing and upon what you were basing figures in order to have a level budget.

Mr. WILLIAMS. It is not fair to characterize that as overruling. It is a question of timing of the process. They submitted their budget in June, the Department submits the budget to OMB in the fall. Congressional action usually intervenes in that period as well as lots of discussions inside the Department as to what seems to be appropriate at that time. As I indicated earlier, when the operating divisions send budgets to the Department, we generally ask them to stay within certain budget guidelines and budget levels associated with the previous year's budget.

HUNGER IN AMERICA

Senator WEICKER. Your prepared statement claims, and I quote, "There is no evidence that the antipoverty activities conducted over the years have had any significant impact on breaking the cycle of poverty."

In contrast to this point of view, the physicians task force on hunger in America, which was just published after its year-long study concluded, and I quote. "The recent swift return of hunger to America can be traced in substantial measure to clear and conscious policies of the Federal Government."

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Their research revealed that many of the hungry were people who had been terminated from food assistance programs. What is your reaction to the "Hunger in America" report?

Mr. VIETH. My reaction to the "Hunger in America" report, I know people are looking at those statistics to seek a conflict with the hunger report put out by the President. As far as ameliorating the poverty, having people rise up out of poverty so they are self-sufficient, the fact that CSBG is used mostly for social service deliveries shows that in fact that hasn't taken place. As far as the report you are talking about from the physicians, I know other people are looking at that now to see how they arrive at those statistics.

Senator WEICKER. Community action agencies all over the country are reporting they would close without community services block grant funds. In my own State of Connecticut, one-half the community action agencies have reported they will be forced to terminate. Would you please provide this committee with the data that supports your contention that repeal of the CSBG Act "should pose no threat to the continued existence of effective community action agencies."

Your proposal to eliminate the community services block grant refers to duplication. Yet there are several human services delivery systems targeted to different populations: VA, the aging programs, the handicapped, and others.

So I have to ask why it is this is the only network the administration is trying to destroy, this network for the poor?

Mr. VIETH. I don't accept the fact we are trying to destroy the network. I think if you have a 12-percent cut a good one should be able to survive, and the language that would be included in the SSBG, they could pick up the services if in fact there was some priority that the State had established. Also with the duplication I think there will be more efficiency, more flexibility in the States to provide these services which are in kind similar services to the SSBG.

Senator WEICKER. How many years have you tried to close the community action agencies?

Mr. VIETH. I have tried 3 years.

Senator WEICKER. I can only say insofar as your actions are concerned on behalf of the various constituencies you are supposed to be an advocate for, it is pretty depressing. I must confess I find it a little hard now considering the conditions of these people that you are supposed to be an advocacy for.

In any event, there is not much point going over this. We have gone over this every year. You are going to lose again.

QUESTIONS SUBMITTED BY THE SUBCOMMITTEE AND PREPARED STATEMENT

Next to present the fiscal year 1986 budget request for the general departmental management, John J. O'Shaughnessy, Assistant Secretary for Management and Budget. He is not here. All right then we will take his testimony at some subsequent hearing.

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Who do we have next? We now have policy research. This morning we will hear from Dr. Robert Helms, Acting Assistant Secretary for Planning and Evaluation who will testify on behalf of the fiscal year 1986 budget request for the policy and evaluation functions administered by his office.

Is Mr. Helms here?

Mr. HOPKINS. Mr. Helms will be here momentarily.

Senator WEICKER. We will also take his testimony at a subsequent hearing.

I have further questions for response to the record, as will other Senators, and a statement submitted by Senator Andrews.

[The information follows:]

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Questions Submitted by the Subcommittee

Question. Last fall, Congress passed legislation creating several new programs which seem to come under the jurisdiction of the Office of Human Development Services. These laws are aimed at strengthening services in such vital areas as family violence and child abuse prevention, training of day care workers, school services for "latch key" children, creation of dependent care information and referral centers, and community food and nutrition services. How can you implement these laws if you request no funding for them?

Answer. The Department has implemented provisions of those statutes for which funds were available or for which appropriations were not necessary. In addition the Department administers a number of programs under existing statutory authority and current appropriations which address concerns in these vital areas.

For example, the Social Services Block Grant provides funds to States which may be used for a wide range of social services, child care services and to prevent and treat the problems of abuse. The Child Abuse and Neglect Prevention and Treatment program also assists States, local governments and voluntary organizations to prevent and treat child abuse and neglect.

The Secretary of HHS will coordinate Federal activities related to the prevention of family violence. The family violence information collection of Project Share, the Department's human services clearinghouse, is being expanded. The National Clearinghouse on Child Abuse and Neglect operates as a national resource for service providers and researchers working in the area of child abuse prevention. Under the Child Abuse and Neglect Prevention and Treatment program $12.5 million will be distributed to the States for child abuse and neglect programs, and $13.5 million for research and demonstration projects addressing child abuse will be awarded this year.

In addition, in March 1985 the Inspector General released a report on preventing sexual abuse in day care programs. An additional $25 million in Social Services Block Grant funds has been made available to States to train child care providers with a particular focus on preventing child abuse.

The Department is publishing regulations which will strengthen guidance already given to Head Start grantees to ensure that children in the program are protected from child abuse and child sexual abuse. It has also published a model child care standards act which provides guidance to States to prevent child abuse in day care facilities. The Department provides support for a number of special research and demonstration projects in these areas under discretionary authorities.

Regarding requests for appropriations under the new authorities, we do not believe that Federal funding through

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narrowly defined "categorical" new programs represents the most effective approach to solving the issues they attempt to address.

Question. Have you proposed that these authorizations be repealed?

Answer. No.

Question. Are there any features of these laws that you can support?

Answer. As I outlined above, there are several ongoing programs and initiatives which already are targeted on solving the issues these new programs attempt to address.

Question. Last June, the Senate Appropriations Committee directed the Administration on Aging to submit a report on respite care services prior to the fiscal 1986 appropriations hearings. What is the status of that report?

Answer. The report on Respite Care Services for the Elderly requested from the Department of Health and Human Services in response to Senate Report 98-544 accompanying the Labor, Health and Human Services Appropriations Act for Fiscal Year 1985 was delivered to the office of Senator Lowell Weicker on March 26, 1985, prior to the appropriations hearing.

Question. Why couldn't you meet the deadline -- isn't nine months a reasonable time?

Answer. As I noted in the previous question, the report on Respite Care Services was submitted to Senator Weicker on March 26, 1985, prior to the deadline.

Question. The Committee has not yet been informed of your intentions regarding report language supporting certain discretionary activities, including legal services projects. Do you intend to comply with the Committee report language in these areas?

Answer. Although we expect that some projects will be funded under each of the topic areas mentioned in report language, we cannot at this time commit to funding any specific projects, organizations, or activities as this would seriously undermine the competitive grant review process. As you know, we award Aging discretionary funds through a competitive process which is now underway. We published an announcement of the availability of FY 1985 discretionary funds and a request for preapplications in the Federal Register on August 23, 1984. "Legal services for the elderly" was one of the priority areas listed in this discretionary funds announcement.

The discretionary funds announcement generated 2700 preapplications. Selection among these for full applications and for final awards depends on the relative merit and each application submitted and the total number and quality of applications submitted within each priority area.

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Question. When do you expect to make final decisions on these matters?

Answer. Decisions on applications to be selected for funding under this announcement will be completed during May and June 1985.

VOLUNTEER CONTRIBUTIONS

Question. Community Action Agencies generate hundreds of thousands of volunteer person hours. There are hundreds of thousands of dollars worth of in-kind contributions, as well as private, local and State funds. Will Social Services Block Grant monies be able to multiply themselves in this way?

Answer. We believe that under the Social Services Block Grant (SSBG), States use volunteers and receive in-kind contributions in much the same way as the CSBG program. Prior to the block grant program, which began on October 1, 1981, States reported on the use of in-kind contributions and volunteer assistance under title XX of the Social Security Act. They reported approximately 500,000 hours per year in some States. States are no longer required to submit this type of information, but we do not believe the program has changed appreciably since that time in regard to these areas.

WIN PHASE-OUT

Question. Your budget justification states "phase-out activities in fiscal 1986 will be carried out with unexpended fiscal year 1985 carryover funds." Does that mean you plan to hold back money appropriated for this program in Fiscal Year 1985, in order to have enough left for phase-out activities.

Answer. The WIN Program has traditionally carried out 10 to 15 percent of allocated funds to assure funding in the work and training contracts for WIN registrants. The official National Coordination Committee Planning Guidance for FY 1985 stated that the State agencies should plan to carryout about ten percent of their resources for contingency planning, to either phase out the program as the Administration plans, or to continue if the Congress mandates.

Question. Will you assure me that the Administration will take no steps to begin phasing out the WIN Program until Congress acts on Fiscal Year 1986 appropriations?

Answer. We intend that the States operate the WIN Program during FY 1985 at the level of client services permitted by the funds made available in the FY 1985 appropriations. Phase-out activities are scheduled to take place early in FY 1986.

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WIN STATISTICS

Question. Your budget justification for the Work Incentive Program states "program data suggest that less than 30 percent of those who found jobs were still employed and off welfare six months later." (Page 200) This appears quite misleading. Isn't it true that actually 60 percent found jobs, but that half of those did not have sufficient earnings at the time of initial placement to remove them from the AFDC rolls?

Answer. The FY 1984 Workload and Output Table in the Congressional Justification shows that approximately 60 percent of those who enter unsubsidized employment left the welfare grant completely because of the employment and earnings; that means less that 50 percent of those still working had insufficient earnings to completely leave the grant.

Question. Isn't the purpose of the Work Incentive Program to give people an incentive to take even low-paying jobs without totally losing their welfare grant -- as a first step toward economic independence?

Answer. Yes, one of the priorities of WIN is to give people an incentive to take entry level jobs, as a step toward economic independence and personal integrity. We believe, however, that our current proposed Work Opportunity Program, by requiring all States to have job search and work activities in place, and by allowing States flexibility in the chosing of which activities to implement, will provide participants with greater opportunity to obtain jobs with longer term potential for advancement and self sufficiency.

GAO REPORT ON WIN

Question. Your opening statement refers to GAO studies which you say demonstrate the WIN Program has not proven to be cost-effective. Are you referring to the June 21, 1982 GAO report on WIN?

Answer. Yes, we are referring to the June 21, 1982 GAO report on WIN.

Question. Isn't it true that the major thrust of the GAO report was that welfare savings were overstated due to reporting deficiencies--problems which have long since been corrected.

Answer. Yes, the major thrust of the GAO report was that the "welfare savings were overstated due to reporting deficiencies." The reporting problems have been addressed in FY 1983, and followup in FY 1984 indicates that the States have implemented the new instructions. No new information exists, however, to

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refute the GAO funding that most WIN participants were capable of finding jobs on their own.

Question. Isn't it also true that the Labor Department, after making the adjustments recommended by GAO, still reports welfare savings more than double the cost of this program?

Answer. The Labor Department and Health and Human Services Department, after making adjustments recommended by GAO, show that the "welfare grant reductions" reported by the State agencies, when annualized and compared to the one-year Federal expenditures, show a savings at a two to one ratio. However, as noted in the June 1, 1982 GAO report, many, if not most participants have sufficient potential to find work on their own without the program.

Question. Has GAO ever said the WIN Program is not cost-effective, or should be abolished?

Answer. The June 1982, GAO report on WIN focusedon modifying "the process for calculating and reporting welfare payment reductions." The GAO report did not specifically address the issue of abolishing the WIN Program; however, it did conclude that most participants did not achieve self-sufficiency and that WIN accomplishments were overstated.

CAP ON FOSTER CARE STATE ADMINISTRATION

Question. You are proposing bill language to override substantive legislation in order to freeze State foster care administrative costs at the Fiscal 1985 level. How much would this cut the amount to which States are entitled under current law for Fiscal 1986?

Answer. Since the entitlement is based on expenditures and expenditures for Fiscal Year 1986 have not been made yet, we cannot give a certain answer. We estimate the savings would be $22 million.

Question. What would be the impact of this cut on State operations?

Answer. We anticipate that the States would likely reduce the claims for administrative costs.

Question. Are you making this legislative proposal to the authorizing committees?

Answer. Our legislation proposal will be sent to the Speaker of the House and the President of the Senate.

TRAINING IN THE PREVENTION OF CHILD ABUSE

Question. The Fiscal 1985 appropriation earmarked $25 million under the Social Services Block Grant for training programs to combat child abuse in day care centers and other

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facilities for children. Do you feel that this money is being effectively used by the States?

Answer. We feel very confident that the additional funds the States have received under the Social Services Block Grant will be fully used to initiate or expand training programs for the prevention of child abuse and neglect.

Question. Why don't you favor extending the authorization and appropriation of $25 million for child abuse prevention training in Fiscal 1986?

Answer. The appropriation of an additional $25 million for Fiscal 1985 under the Social Services Block Grant was enacted as a one year only financial incentive to encourage States to initiate training programs primarily to combat child abuse in day care centers and other facilities for children. Funds for training purposes in Fiscal 1986 and subsequent years will continue to be available to States under the $2.7 billion Social Services Block Grant and from the child abuse and neglect grants which States receive.

IMPACT OF STATE GRANT LEVEL FUNDING

Question. You recommend flat funding for the Developmental Disabilities State Grant Program for fiscal year 1986. This is equal to a 4.7 percent cut with the inflation factor. Considering that "employment related activities" was added as a State priority must last year, and that it will be a mandatory priority after 1986, how will States be able to begin new services in this critical area with less money?

Answer. In fiscal year 1984, at a lower budget level, twenty-four States had already elected to provide employment related services under the Basic State Grant Program. The mandatory provision of employment related activities in all States does not begin during the period covered by this budget request. Since we do not have a fiscal year 1987 budget request at this time, it is not possible to directly address the effect of this provision in fiscal year 1987.

ELIMINATION OF SPECIAL PROJECT SUPPORT

Question. You recommend eliminating Special Projects for the Developmentally Disabled, which are currently funded at $2.7 million. This is the only targeted research and development fund for the special needs of developmentally disabled persons. In the past, projects funded have provided critical information which led to improvements in services for developmentally disabled persons. Is there no more need for research and development in this area?

Answer. In fiscal year 1986 no new budget authority is requested for Special Projects. This is consistent with the Administration's policy to limit discretionary funding, and to target funds on service programs. High priority research and demonstration activities may continue with Basic State Grant and University Affiliated Facility funds.

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Question. The Attorney General's Task Force on Family Violence recommended that "the Federal Government should provide financial incentives and encouragement to the States to train criminal justice personnel, to conduct a family violence prevention and awareness campaign, and to maintain temporary residential facilities for victims of family violence." In view of this Administration report, why didn't you request funding to implement the recently enacted Family Violence Prevention and Services Act?

Answer. We believe a new Federal program to address family violence is duplicative of existing Federal activities.

There are numerous Federal support programs addressing different aspects of family violence. These programs can assist local governments in their efforts to combat the crime of family violence. Within the Department of Health and Human Services alone, there are a number of programs. For example, the Social Services Block Grant provides funds to States which may be used for a wide range of social services, including those that may address family violence. The Department also funds a number of research projects examining the issue of family violence.

The creation of an additional narrowly defined categorical program as authorized in P.L. 98-457 provides for an inappropriate Federal role in issues which are best addressed by local communities. A Federal categorical grant program to deal with the problems of family violence is inconsistent with the Administration's objectives of allowing States and local communities maximum flexibility in addressing local problems. The most effective responses to the problems of family violence are those developed by local communities, not new, cumbersome, and administratively complex categorical programs.

DEPENDENT CARE SERVICES: NEW LEGISLATION

Question. Last October, new legislation was enacted which authorized $20 million for each of Fiscal Years 1985 and 1986 for Grants to States for Planning and Development of Dependent Care Programs. What is the rationale, other than budgetary reasons, for the Administration's failure to request appropriations to implement this new law?

Answer. We do not believe that the most effective approach for responding to community issues -- such as school-age day care and dependent care resource and referral -- is necessarily yet another narrowly-defined Federal categorical program. Under this approach, the Federal government not only takes primary responsibility for paying for the program, but also for defining the problem, and defining to very specific levels of detail what the solution ought to be. This disregards the many valuable programs already underway through State and local programs, through private employers, through school and volunteer programs, and through parent cooperative programs. In addition, Federal funding for these activities is already available through the Social Services Block Grant, which is consistent with the Administration's policy of allowing States and local communities maximum flexibility in addressing local problems.

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DEPENDENT CARE SERVICES

Question. What State resources are available for before and after school facilities?

Answer. The primary State resources available for before and after school facilities include State tax revenues and Federal funding from such programs as the Social Services Block Grant and Child Welfare Services.

Question. How many States provide funds specifically for information and referral centers?

Answer. All States have information and referral centers, usually funded with Social Services Block Grant resources for which States have no reporting requirement. While we have no Federal data on which to base estimates of expenditures, assuming that this question refers to child care, the December 1984 Directory of Child Care Information and Referral Agencies includes 185 agencies which offer these services to the general public in 48 States and the District of Columbia.

Question. Provide for the record a State-by-State estimate of amounts spent for each of the "Latch Key" and information and referral activities.

Answer. We do not have this information because States are not required to report it.

REGIONAL RESOURCE CENTERS

Question: Both House and Senate Appropriations Committee reports urged you to continue funding the ten regional resource centers for children, youth and families. What is the current status of these centers?

Answer. Federal funding of the ten Regional Resource Centers terminated September 30, 1984.

Question: When do you intend to make funds available for their continued operation?

Answer. A Federal Register Notice announcing availability of funds for new competitive grants for Resource Centers for Child Welfare Services was published April 1, 1985. The closing date for receipt of grant applications is June 17, 1985. Any of the formerly funded centers may apply. Applications will be reviewed competitively, and grants will be awarded by September 30, 1985.

FUNDING FOR AGING RESEARCH, DEMONSTRATION AND TRAINING

Question. Describe the types of projects which have had to be eliminated due to reductions in Research, Demonstration and Training since 1980, under Title IV of the Older Americans Act.

Answer. As discretionary resources have declined, the Administration on Aging has considered the impact of its discretionary in-

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vestments and has implemented a discretionary funds strategy which is targetted on priorities mandated by the Older Americans Act and Administration policy. The changes in types of discretionary projects reflect primarily changes in priorities rather than reductions in resources.

Question. How has this reduction affected the number and types of persons to be trained for work in the field of aging?

Answer: While it is not clear how the number of persons trained will be affected, it is likely that a variety of occupations supported will continue to expand. During the past several years the Administration on Aging has financed the development of training activities for a great range of occupations which work with or for the elderly, especially through the Allied Professions Program. This emphasis is expected to continue.

NATIONAL MINORITY AGING ORGANIZATIONS

Question. What are your plans for funding the four major national minority organizations, i.e. the National Caucus and Center on Black Aged; the National Association for Hispanic Elderly; the National Pacific/Asian Resource Center on Aging; and the National Indian Council on Aging?

Answer. The four national minority organizations have submitted applications under the Fiscal Year 1985 OHDS Coordinated Discretionary Funds Program. These applications are currently under review and final decisions will be made in June 1985.

Question. Will each of these organizations be funded at the same level as in fiscal 1984? If not, why not?

Answer. In view of the current status of these applications, we cannot anticipate the level of funding at this time.

GERONTOLOGY CENTERS

Question. What is your plan for funding Long-term Care Gerontology Centers in Fiscal Years 1985 and 1986?

Answer. The Long-term Care Gerontology program is currently undergoing a comprehensive review.

EVIDENCE FOR DUPLICATION OF SERVICES

Question. Many States are required by State law to develop an impact statement on duplication of programs. If the States are certifying that their social services block grant and the community services block grant are not duplicate, how can you say they are, particularly when you don't make any effort to gather data on the community services block grant program?

Answer. We know that there are many services provided under the SSBG that can also be provided under the CSBG, such as day care and protective services. Our position is that the

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Federal statutory authorities are essentially duplicative in that they both permit the States to choose among virtually the same wide range of possible social services.

CUT IN SOCIAL SERVICES FUNDING

Question. Five years ago, combined appropriations for the Social Services and Community Services Block Grants totaled $3.7 billion. By fiscal year 1985, funding declined to $3.1 billion. Now you are proposing a further cut to $2.7 billion in combined appropriations for fiscal year 1986. What services do you expect would be reduced with another $400 million cut?

Answer. Because each State determines its own priorities based on the needs of the people to be served and the effectiveness of programs within the State, it would be difficult for the Department to identify services that might be reduced. We would expect that if reductions in services were necessary, lower priority services, as defined by each State, might be affected.

IMPACT OF INCREASE FOR PROTECTION AND ADVOCACY

Question. In fiscal 1985, the Protection and Advocacy Systems received a funding increase of 64 percent. How are States using this increase in funds and what are the major outcomes that can be expected from this increase in advocacy activity?

Answer. States are required, under Public Law 98-527, to provide annual reports to the Administration on Developmental Disabilities on program activities and accomplishments. The first reports, covering fiscal year 1985, are due January 1, 1986. A report based upon this information is due to be submitted to the Congress in April 1986. However, the contacts to date with State agencies suggest that the increased funds are being used effectively to expand support for the legal and human rights of persons with developmental disabilities.

Question. The 1984 amendments to the Developmental Disabilities Act increased the minimum State allotment for the Protection and Advocacy Systems from $50,000 to $150,000. Have minimum allotment States been able to effectively use this funding increase and in which ways have services been expanded?

Answer. States are required, under Public Law 98-527, to provide annual reports to the Administration on Developmental Disabilities on program activities and accomplishments. The first reports, covering fiscal year 1985, are due January 1, 1986. A report based upon this information is due to be submitted to the Congress in April 1986. However, the contacts to date with State agencies suggest that the increased funds are being used effectively to expand support for the legal and human rights of persons with developmental disabilities.

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STATUS OF CONGRESSIONALLY MANDATED REPORT

Question. The Developmental Disabilities Act requires HHS to submit a report to Congress on April 19 of this year outlining recommendations for improving services to mentally retarded people. The report is to be a collaborative report between HHS, the Department of Special Education, and the National Council on the Handicapped. What is the status of the report?

Answer. The lead for developing this report is with the Office of the Assistant Secretary for Planning and Evaluation. Departmental staff have been considering ways in which services could be improved in order to better promote independence, productivity, and integration into the community of persons with developmental disabilities. A draft report is now underway.

WIN STUDIES

Question. Your budget justification states (page 200) that "Repeated Studies by the General Accounting Office and Private Contractors have shown that the WIN Program is not cost-effective." Specifically, which studies are you referring to?

Answer. We are referring to (1) the GAO report, "An Overview of the WIN Program: Its Objectives, Accomplishments, and Problems" of June 1982; and (2) the KETRON study "The Long-Term Impact of WIN II: A Longitudinal Evaluation of the Employment Experiences of Participants in the Work Incentive Program," final report January 1980.

Question. Please provide a copy of the summaries of these studies for the record.

Answer: Attached are copies of the summaries of the GAO and KETRON reports.

COMPTROLLER GENERAL'S REPORT TO THE RANKING MINORITY MEMBER, SUBCOMMITTEE ON OVERSIGHT OF GOVERNMENT MANAGEMENT, SENATE COMMITTEE ON GOVERNMENTAL AFFAIRS

AN OVERVIEW OF THE WIN PROGRAM: IT'S OBJECTIVES, ACCOMPLISHMENTS, AND PROBLEMS

D I G E S T

The Work Incentive (WIN) program is supposed to help recipients of Aid to Families with Dependent Children (AFDC), one of the largest Federal and State welfare programs, to get jobs through a program of training, work experience, and employment while reducing the cost of the AFDC program.

Because of concerns raised about the WIN program and WIN-type work incentives, in June 1980 Senator Carl M. Levin, then Chairman of the Subcommittee

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on Oversi t of Government Management, Senate Committee on Governmental Affairs, requested that GAO assess the program.

GAO designed its assessment to be projectable nationwide to determine:

--What portion of the AFDC population receives assistance from WIN.

--What percentage of WIN participants achieve self-support.

--Whether other WIN performance goals are being achieved.

--What mix of services is being provided to WIN participants and to what extent those services and other factors are associated with participant outcomes.

GAO visited 150 WIN offices in 40 States and gathered data on 2,229 WIN participants. (See pp. 7 to 9.)

MOST ADULT AFDC RECIPIENTS DO NOT PARTICIPATE IN THE WIN PROGRAM

Because of budget limitations and legal exemptions from the WIN program, less than 20 percent of the 4.1 million adult AFDC recipients participated in the program in 1980. The Department of Health and Human Services estimated that over 60 percent of the adult AFDC recipients were legally exempt from registering for WIN, mainly because they were caring for a child under 6 years of age.

Limited funding and the higher costs involved with helping the less employable forced most WIN offices to serve those that were readily employable. Also, the incentives in the fund allocation formula put a premium on how many got jobs without regard for the help provided. As a result, WIN assisted AFDC recipients who were easiest to place in a job--those most likely to get jobs without WIN help. The other AFDC recipients who registered for the WIN program but were not selected to participate in a WIN component generally did not get any help. (See pp. 12 and 13.)

Many WIN participants had sufficient potential to find work on their own. For fiscal year 1980, about 70 percent of the 204,000 WIN registrants who entered employment said they found their own jobs. About half of those who entered employ-

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ment said that being in the WIN program contributed to their finding a job. (See p. 16.)

SOME WIN PARTICIPANTS ELIMINATED OR REDUCED THEIR AFDC GRANTS, BUT MOST DID NOT ACHIEVE SELF-SUFFICIENCY

WIN officials reported that about 36 percent of the AFDC recipients actively participating in WIN entered employment during the fiscal year. Of those that got jobs in fiscal year 1980 who were on AFDC, 40 percent of their jobs paid enough for them to go off AFDC as soon as they started working. The other 60 percent of the jobs required that the WIN participants continue to receive full or partial AFDC grants. When the WIN participants were interviewed 6 to 18 months later, 64 percent were still working, and 38 percent were working and off AFDC. (See pp. 19 to 21.)

Once WIN participants got jobs and earned enough to become self-sufficient, they tended to remain in a working status; however, those who got jobs but did not earn enough to go off AFDC tended to lose their jobs. For fiscal year 1980, half of the WIN participants who got jobs but continued to receive a full AFDC grant were not working when they were later interviewed. In comparison, only one-third of those who got jobs that paid enough to get off AFDC were no longer working when interviewed.

Furthermore, a statistically significant relationship existed between the participants' marital status, education level, number of children, years on AFDC, and age and whether they maintained their employment and were off AFDC when they were interviewed. WIN participants who were married, were better educated, had fewer children, had fewer years on AFDC, and were younger had a greater likelihood of sustaining their employment and getting off AFDC than did other participants.

However, no statistically significant relationship was found between conditions associated with geographic location, such as unemployment rates and community size or participation in WIN training components, and participant employment and AFDC status at the time of the follow-up interview. (See pp. 23 to 30.)

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WIN ACCOMPLISHMENTS OVERSTATED

The measures of accomplishment most often used by WIN officials are the number of participants entering employment; the job retention levels; and the savings resulting from AFDC grant reductions and reductions in other related programs, such as Medicaid and food stamps. However, because of the double counting of individuals entering employment and the use of unrealistic retention levels in calculating savings from AFDC grant reductions, GAO estimated that reported fiscal year 1980 accomplishments of $632 million were overstated by $319 million. (See pp. 34 to 37.)

Further, WIN officials did not consider the limited impact that the program may have had on many participants. As a result, reported savings figures do not separate the savings resulting from self-placements from those resulting from WIN placements. GAO estimates that $91 million of the savings was attributable directly to WIN placements and $222 million to self-placements. (See pp. 38 and 39.)

RECOMMENDATIONS TO THE SECRETARIES OF LABOR AND HEALTH AND HUMAN SERVICES

The Secretaries should modify the process for calculating and reporting welfare payment reductions by

--eliminating the double counting of participants who enter into more than one job in a year;

--using a more realistic retention level, such as the 6-month level; and

--identifying the welfare savings related to WIN placements separately from the savings resulting from participants' self-placements. (See pp. 39 and 40.)

AGENCY COMMENTS

The Department of Health and Human Services deferred comments to the Department of Labor, which concurred in our recommendations. However, Labor is not planning to implement the recommendations because the administration proposes to replace the WIN program in fiscal year 1983 with a combination of

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--mandatory Community Work Experience Programs,

--activities authorized under the Job Training Act of 1982, and

--human services and other block grants. (See p. 40.)

The Secretaries of Labor and Health and Human Services should consider GAO's recommendations in establishing reporting requirements for any program which replaces the WIN program. If WIN is continued beyond this year, the recommendations should be implemented.

REPORT MEL 79-16
CONTRACT NO. 53-42-77-02

THE LONG-TERM IMPACT OF WIN II:
A LONGITUDINAL EVALUATION OF THE
EMPLOYMENT EXPERIENCES OF PARTICIPANTS
IN THE WORK INCENTIVE PROGRAM

FINAL REPORT
JANUARY 1980

Net WIN Impact

1. The annual decay of the net WIN impact on the earnings of men is astonishingly rapid. Our estimate of this figure suggests that about 91 percent of the first year benefit vanishes in the second year following WIN and that the total lifetime earnings benefit attributable to WIN for the average male may only be $494. The first year earnings benefit for women is only about $286, but the estimated annual decay rate of 23 percent yields a projected lifetime amount of about $1,318.

   The increase in male participant earnings is primarily attributable to increases in employment. However, the earnings of female participants improve because of higher wage rates, as well as increases in employment.

2. The net impact of WIN on welfare grant reduction is quite modest for both men and women -- on the order of $5 to $15 for the monthly AFDC grant (plus work related expenses). There is only a net decrease of one to three weeks in the time spent on welfare in the year following WIN participation.

3. Both men and women at higher education levels gain more from participation in WIN than men and women with lower levels of education. The estimate of impact on earnings in the first year following WIN for men with 12 or more years of schooling is about $650 and for similarly educated women, the impact is about $311. Also, men and women with no prior occupation before WIN entry experience gains in

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annual earnings in the first year of $1,208 and $462 respectively. Both of these findings suggest selection priorities for WIN intake that could improve the average level of WIN benefit on participant earnings.

Differential WIN Impact

4. Work experience is a WIN component provided almost exclusively for women and our impact estimates indicate that the component is extremely successful for them. One of our most important evaluation findings is that the impact of WIN work experience on the annual earnings of women is about $500 in the first year and appears to build up from there in succeeding years. The building process is apparently of such a magnitude that it is not reliably estimated with our usual techniques. Instead, a simple average benefit computed over three years following WIN participation and projected over the lifetime of the women yields an estimate of total earnings gains of $23,530.

5. Vocational training exhibits a surprisingly positive effect on the earnings of women by producing a building of benefit equal to one to two percent a year. If this buildup rate is used to project gains in earnings for women, we estimate that they will achieve a lifetime gain over their counterparts in the comparison group of about $15,797.

   Perhaps because of the small sample size, the estimate of the effect of vocational training on the earnings of men is eccentric. After some large gains in the first six months following WIN (about $300 during this period), the earnings impact on men plummets to negative values and remains negative for about one year. At this time (18 months after leaving WIN), the earnings begin to steadily improve right up to the end of the three-year observation period. Since the impact is building in the second half of the observation period, it is impossible to predict when the buildup will level off or decline. The average annual impact computed for this period is about $215.

6. On-the-Job Training (OJT) is quite effective in raising the annual earnings of both men and women. The earnings gain in the first year for men in OJT is about twice the value for women ($1,964 versus $903). However, the benefit in succeeding years decays at a much higher rate for men (26 percent) than for women (16.5 percent). The difference in decay rates tends to somewhat equalize the estimate of total lifetime earnings gain for men and women -- the total benefit estimate for men is $7,726 and about $5,130 for women.

   Both men and women with no prior occupation achieve higher levels of earnings gain from OJT than other men and women. In the first year following WIN, men who previously had no occupation enjoy an increase in annual earnings of $3,401. Similarly situated women achieve gains of $1,652 in that first year.

7. Public Service Employment (PSE) contributes strongly to the earnings gains of men and women after the subsidy period ends. The estimate of impact on annual earnings in the first year following WIN is $2,146

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for men and $1,494 for women. The annual decay rate on the male benefit is very high (45 percent), however, the annual decay rate for women is relatively low (10.6 percent). Because of the lower decay rate for women, their projected lifetime gain in earnings attributable to PSE is larger than the estimate of total benefit for men ($14,635 for women versus $5,230 for men).

8. Job placement assistance, provided without any other WIN training or employment component, is of little value in increasing the annual earnings of men and women. Moreover, the large numbers of WIN participants who receive only job placement assistance tend to dilute the effect of the intensive components (that is, work experience, vocational training, OJT and PSE) to such an extent that the overall WIN program appears to have only modest effects on the annual earnings of participants.

Benefit/Cost Analysis

9. Given the assumptions we have made (see Chapter VI), we arrive at the following conclusions:

- The net benefits of the program do not exceed average program costs for either men or women regardless of the length of participation in it.
- WIN work experience, because of its relatively lower costs, is the most cost-effective component for women.
- Vocational training is cost-effective for women and ranks higher than OJT and PSE.
- OJT and PSE are both cost-effective and are assigned approximately the same rank.
- Even with lower costs, the impact of job placement assistance, without training or employment components, is so small that this service is not cost-effective.

Our overall conclusion is that work experience, vocational training, OJT and PSE are strong pillars of the national WIN program, but that other program services, such as job placement assistance alone, do not yield cost-effective results.

EXECUTIVE SUMMARY

Unlike other evaluations of the WIN program, we believe this study of WIN to be unique for several important reasons. First, the sheer size and scope of the evaluation, more than anything else, permits an indepth examination of various facets of the program that is not possible in a smaller scale evaluation. Not only have we estimated the impact of the program as a categorical entity affecting the employment and welfare experiences of a substantial portion of the employable AFDC population, but we have penetrated

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beneath the surface of WIN and sifted through the services offered to determine which are effective in meeting program goals. The second important feature of this evaluation, in comparison to earlier efforts, is the three-year period of post-program follow-up in which program impact can be estimated, tracked, and projected into the future.

An evaluation of this magnitude is not without its fair share of difficulties. Large volumes of data from alternate sources must be collected, organized and rigorously analyzed, before conclusions can be drawn even tentatively. Additionally, as the length of the follow-up period becomes longer, the further the program being evaluated recedes into the past, thus making the findings more tenuously related to the current program. The extent to which the findings presented in this report can be extrapolated to the present is problematic. There is certainly evidence that the WIN program and the labor market environment in which it operates have undergone some changes since the evaluation was initially undertaken. However, there is no good reason to believe that the major findings would be substantially altered in a present-day context.

With these cautious thoughts as an introduction, this section contains some of the major findings and highlights of the long-term longitudinal evaluation of the WIN program.

DUPLICATION OF SERVICES BETWEEN BLOCK GRANTS

Question. Some States have specifically designated the Community Services Block Grant monies to be used for mobilization of resources and institutional change for the poor -- Michigan and Massachusetts are examples of this. Are you telling us the Social Services Block Grant can continue these functions?

Answer. Currently the CSBG and the SSBG have essentially the same purposes, goals and objectives, and almost all the activities authorized under the CSBG can be carried out under the SSBG. An amendment to the SSBG has been prepared for introduction in the Congress, to add a new goal of alleviating poverty to the explicit statutory goals stated in the SSBG, thus making it clear that funds under the SSBG Act may be used to support activities for many of the same purposes as in the CSBG.

LOW PRIORITY SOCIAL SERVICES

Question. You say States can be expected to drop low priority activities in order to support Community Action Agencies. Would you list for us some low priority activities that are being funded by States under the Social Services Block Grant?

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Answer. The determination of what is a low priority activity is a decision that would be made by each State based on the needs of the people to be served and the effectiveness of programs within the State both under the SSBG and the CSBG.

Question. Social Services Block Grant reporting does not require a ranking of priority programs. Most States do not have sufficient funds to fund further down on their list than the top three priorities. How would you define a "low priority" for human service needs?

Answer. Information provided by the States in their annual pre-expenditure reports on the SSBG show that they all provide a variety of social services and all provide more than three services with several States providing 23 services in Fiscal Year 1984. As indicated in my earlier response, the definition of "low priority" is one that would vary from State to State depending on the particular needs of the State.

GAO REPORT/FOSTER CARE

Question. In August of 1984, the General Accounting Office recommended that you revise Foster Care program regulations to ensure that all the improvements and safeguards mandated by law are adopted by the States. How have you responded to the GAO findings and recommendations?

Answer. Yes. The Department generally agreed with the recommendations of the General Accounting Office. Revised regulations have been developed and are now under review. These proposed regulations address the specific concerns raised by GAO.

ECONOMIC DEVELOPMENT

Question. Over 50% of the Community Services Block Grant funds are used for programs for the poor. In some States the thrust has been to use these funds for economic development projects. Is there a Social Services Block Grant program anywhere in the country doing economic development?

Answer. We do not require the States to report to us on specific projects. However, the goals of the SSBG (section 2001) include "achieving or maintaining economic self-support to prevent, reduce, or eliminate dependency" and services allowed include such activities as employment services, training and related services, information, referral, and counseling services.

Question. It appears the Administration has changed, at least twice in the past four years, its listing of programs in the Federal safety net for the poor.

Are you able to tell us what programs the Administration currently counts as being in the "safety net"?

Answer. The HHS programs included in the safety net are: Medicare, Social Security, Supplemental Security Income, Assistance Payments (AFDC), and Child Support Enforcement.

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Question. The Community Services Block Grant provides direct funding to Indian tribes upon the request of the tribe and based on need. The Social Services Block Grant does not. What protections do you foresee for Federally recognized Tribes under the Administration's proposal?

Answer. During the Ninety-eighth Congress the Administration proposed legislation to Congress in two separate bills which would have repealed the Community Services Block Grant and which would have added a clause to the Social Services Block Grant to provide for direct funding to Federally recognized Indian tribes. We expect to send similar proposals to the Congress later this year as referenced in our budget documents.

Question. Last fall, Congress added a new title VII to the Older Americans Act, authorizing $8.5 million for health education and training programs. If Congress were to fund this program, which agency in HHS would be responsible for implementing it?

Answer. We have no plans to implement this duplicative program.

Question. Exactly how would these funds be used, and how would HHS administer the program?

Answer. No plans exist to administer this program.

USE OF BLOCK GRANT FUNDS

Question. Your Budget Justification material for the Social Services and Community Services Block Grants totally omits a discussion of how appropriations were spent in Fiscal 1983, as well as plans for Fiscal 1984. Are you saying that you collect absolutely no data from the States on how these funds are used?

Answer. We do not collect specific data from the States as they are not required under the authorizing legislation to submit detailed information on the operation of their programs. We do obtain general information from States on the intended use of their funds. Under the SSBG, States are required to prepare reports on how the funds were used at least every two years. The block grant legislation and regulations place primary accountability on State oversight processes, audits, and the requirement for public involvement in the development of a State's social service program.

Question. Would it not be useful to know the priorities States are putting on services such as Day Care, Child Protection Services, and Preventing Abuse of Children and Adults?

Answer. We do receive general information from the States which reflect their priorities based on the services they expect to fund during the coming Fiscal Year. In general, we think the question of usefulness needs to be balanced against the cost to the States of requiring additional information.

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HEAD START/CDA ASSESSMENT AND CREDENTIALING

Question: Why in the request for proposals issued on January 29 does the Department announce its intentions to spend $2 million over 30 months for a national system for CDA assessment and credentialing when Head Start's authorizing legislation mandates that $1.8 million be spent annually for these functions?

Answer: We believe that the authorizing legislation requires that Head Start spend $25 million on training and technical assistance activities but it does not require a specific level of expenditures for CDA. The Department is complying with the $25 million training and technical assistance requirement.

Nevertheless, we expect to spend $7.35 million on CDA in FY 1985, approximately the same level as in 1982 and each succeeding fiscal year.

Question: What is the rationale for the requirement that "the successful applicant will be responsible for the establishment of a fee structure which will generate sufficient income to permit operation of the national accreditation and credential programs after the completion of the federal funding period" if HHS plans to as the authorizing language requires to continue to support a national CDA assessment and credentialing program?

Answer. The Department intends to continue to support the CDA program. However, our concern is that the CDA credential as currently structured is not fulfilling its tremendous potential. For example, in 1984 fewer than 2,400 individuals received the CDA credential, well below the 3,000 person level we had funded the current operator to credential. The quality of CDA training varies greatly, with no common quality standards being applied across the training programs. The current system is expensive; credentialing fees for the individual are $325.

To expand and improve the quality and acceptance of CDA, we have proposed a restructuring of the CDA. This involves establishing for the first time standards for CDA training and applying these standards to training programs through a formal accreditation or approval process. Training institutions would be responsible for providing assessment for CDA trainees. The leadership is to be provided by a central CDA body broadly representative of the child care field which would be responsible for setting standards for training, reviewing compliance of the training programs with the standards, awarding the CDA credential and renewing the credential periodically. We believe that this approach is fully consistent with the Congressional intent with regard to support for the CDA credential.

As a result of these reforms we expect many more training institutions to offer CDA training, thereby expanding training opportunities nationwide. With the improved quality of CDA training resulting from the application of common standards, we

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expect greater acceptance of the CDA throughout the child care field, greater value placed on the credential and greater demand for it. Also, as fees from the training programs for the accreditation or approval process begin to support the national CDA body, costs to the individual for the CDA credential should decrease. In effect, the CDA credential will be following the development path of other professional credentials.

In future years, assuming the successful restructuring of the CDA program, our intention is to provide funds freed up from the central grant directly to local grantees to assist with the costs of training and assessment.

Question. If the assessment process is decentralized, how does the administration plan to assure quality control?

Answer. We have proposed a change in the CDA delivery system so that in the future, under the leadership of a national CDA body which will develop and promulgate standards, both training and assessments would be provided at the community level by approved institutions. We expect the central CDA body to work closely with the early childhood field to maintain high quality training and objective assessments, and we believe that approval of institutions by a central CDA body for these purposes will insure that this happens. The CDA credential would continue to be awarded and periodically renewed by the central CDA body.

FOSTER CARE, CHILD WELFARE SERVICES, ADOPTION ASSISTANCE

Question. How many States complied with the foster care protections required by Sec. 427 of the Social Security Act for receipt of foster care and child welfare services incentive funds (under titles IV-B and IV-E) in FY 85?

Answer. We have not conducted compliance reviews for Fiscal Year 1985. These reviews will be done in Fiscal Year 1986. However 50 of the 55 States and jurisdictions who certified their compliance for Section 427 incentive funds are receiving these funds for Fiscal Year 1985. Compliance reviews are conducted retrospectively.

Incentive funds are available only under title IV-B - if a State meets the requirements of Section 427 (a) and (b) it may transfer unused IV-E funds to title IV-B.

Question. How many States self-certified in FY 81-84 but were later found not to be in compliance?

Answer The information requested is shown in the following table:

For FY 1981 -- 34 States and jurisdictions were self-certified
25 were approved
4 were denied
5 States withdrew their certification

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For FY 1982 — 42 States and jurisdictions were self-certified
34 were approved
6 were denied
1 withdrew its certification
1 is still to be reviewed

For FY 1983 — 48 States and jurisdictions were self-certified
32 were approved
5 were denied
6 have decisions pending
5 are still to be reviewed

For FY 1984 — 49 States and jurisdictions were self-certified
27 were approved
4 have decisions pending
18 are still to be reviewed

Question: What are your procedures for determining whether a State is complying?

Answer. Following a State's certification for Section 427, the Administration for Children, Youth and Families conducts a review of the administrative procedures of the State to assure that the statutory and regulatory requirements of Section 427 are met. Only if the State achieves 100 percent compliance at the administrative procedures review level does the Adminstration for Children, Youth and Families move to the second part of the review, the case record survey.

For the first year in which an Initial Compliance Review is conducted at least 66 percent of the State's cases that are reviewed must be found acceptable. Once a State achieves initial compliance, a Subsequent Compliance Review is held the following year and the State must demonstrate that at least 80 percent of the cases reviewed meet the requirements.

Once a State achieves the subsequent level of eligibility, it does not have another compliance review until three years later. This review, called the Triennial Compliance Review, requires a State to reach a level of 90 percent of cases reviewed being deemed acceptable. Once a State reaches triennial eligibility, reviews are conducted every third year and the 90 percent level of acceptable cases must continue to be met.

Question. Is this procedure implemented in all States that have certified compliance?

Answer. Yes, this procedure has been implemented for all States that have certified compliance.

Question. Has this procedure changed since FY 83? If so, how?

Answer. No, this procedure has not been changed since fiscal year 1983.

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Question. Have revised criteria for compliance been published (since the 1983 regulations) to help States establish the necessary foster care protections? If not, why not?

Answer. We have not seen a need to change the criteria in the 1983 regulations. We have issued and will continue to issue a series of Program Instructions, Policy Interpretation Questions, Information Memoranda and Policy Announcements to assist the States in understanding and implementing the requirements of P.L. 96-272 and section 427 in particular.

Question. What is the status of States found not to be in compliance after having received the incentive funds? Have the States reimbursed HHS?

Answer. States not in compliance are ineligible to receive incentive funds or to transfer funds. We have recovered all the incentive funds.

Question. What is the anticipated impact of the extension of the incentive provisions through FY 85 under the Social Security Amendments of 1984?

Answer. The Social Security Amendments of 1984 allow the States to continue to receive incentive funds and therefore strengthen the child welfare program.

CHILD WELFARE DATA COLLECTION

Question. Are there hard data on the number of children placed for adoption each year in the U.S., the number free for adoption, and the numbers being served by various Federal programs?

Answer. We have only partial data from public adoption agencies and none from private agencies. However, the Assistant Secretary for Human Development Services has established an inter-agency task force to investigate and report on the number of children free for adoption, placed for adoption and served. This inter-agency task force on adoption data is presently analyzing these issues and will make recommendations on how to improve adoption data by this summer. The American Public Welfare Association operates voluntary data collection activity on several programs and is making strong efforts to improve the adoption data component.

Question. Why isn't such information available?

Answer. No one agency, save the State Courts, has responsibility for all adoptions. These State Courts are not under the jurisdiction of any Federal agency. However, some discussions between the inter-agency task force on adoptions with State Court representatives has yielded a willingness on both sides to work towards developing better data on overall adoptions and characteristic data about children being adopted.

Question. Can the success of various Federal programs be evaluated without such data?

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Answer. Yes, description data are useful in giving an impression about programs. However, we believe the success of a program can be evaluated without large amounts of highly specific data. While data about system outcomes such as adoptive placement are useful for tracking certain aspects of a program's performance, these data cannot be used for evaluation of agencies or adoption programs in any real sense.

Question. How?

Answer. Evaluation of success is generally performed on a specific aspect of performance such as we have done in voluntary foster care placement, adoption assistance, case review system, dispositional hearings, pre-placement prevention and reunification. The sum of such studies can provide a fairly clear picture of how well a program is doing.

Question. Section 476 of the Adoption Assistance and Child Welfare Act authorizes the Secretary to require States to submit information on children receiving adoption or foster care services. Why haven't you acted on this authority to get annual data?

Answer. We have elected to meet the requirements of Section 427 through a voluntary cooperative information system operated through the American Public Welfare Association. We feel the experience to date indicates good acceptance of this approach by the States.

FUNDING FOR AGING RESEARCH, DEMONSTRATION AND TRAINING

Question. Describe the types of projects which have had to be eliminated due to reductions in Research, Demonstration and Training since 1980, under Title IV of the Older Americans Act.

Answer. As discretionary resources have declined, the Administration on Aging has considered the impact of its discretionary investments and has implemented a discretionary funds strategy which is targetted on priorities mandated by the Older Americans Act and Administration policy. The changes in types of discretionary projects reflect primarily changes in priorities rather than reductions in resources.

Question. How has this reduction affected the number and types of persons to be trained for work in the field of aging?

Answer: While it is not clear how the number of persons trained will be affected, it is likely that a variety of occupations supported will continue to expand. During the past several years the Administration on Aging has financed the development of training activities for a great range of occupations which work with or for the elderly, especially through the Allied Professions Program. This emphasis is expected to continue.

OLDER AMERICANS HEALTH EDUCATION AND TRAINING

Question. Last fall, Congress added a new Title VII to the Older Americans Act, authorizing $8.5 million for Health Education

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and Training Programs. What is the rationale for not requesting appropriations to implement this legislation?

Answer. The Administration on Aging has a long and excellent record supporting nutrition and health for older Americans and considers both elements as essential to the Older Americans Program. Over the years, we have funded health and nutrition education programs under Titles III, IV and VI. We continue to do so today. As you know, when Title VII was first introduced as a bill, this Administration did not support its enactment. We stated then, and continue to believe, that the Administration on Aging can and does support, under existing titles, the essential components of health education and training that would be provided under Title VII. We do not see any advantage to establishing a new rule for these activities at this time, especially in light of current budget restraints and diminishing resources.

CONTRIBUTIONS FOR MEALS

Question. For the record, can you supply data on the average contribution made by nutrition services participants in the years since the Administration on Aging launched its program contribution initiative?

Answer. Management improvement initiatives, one of which is increases in program income, began in Fiscal Year 1982. Using Fiscal Year 1981 as a base year, contributions have increased each year since then. The average contributions per meal for Fiscal Years 1982 through 1986 are as follows.

1982 ..... 47¢
1983..... 51¢
1984 ..... 53¢
1985 (Est.).... 56¢
1986 (Est.).... 59¢

Question. How many more meals has the increase in program contributions generated over the past several years?

Answer. Many things contribute to an increase in numbers of meals. Not only contributions, but improved techniques such as performance-based contracting and other management improvements, and improved return on Federal investment affect the services provided.

FUNDS FOR IN-HOME SERVICES AND HOME-DELIVERED MEALS AS COMPARED TO FUNDS FOR CONGREGATE NUTRITION

Question. In view of the increasing numbers of persons over age 75 who may be in need of in-home supportive services, do you think more emphasis should be placed on the supportive services and home-delivered meals components of title III than on the congregate nutrition program?

Answer. We believe that the Older Americans Act provides sufficient flexibility for each State and local community to respond to the unique needs of its own population of older persons. The 1984

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Amendments have increased the authority of States to transfer funds between supportive and nutrition services--to 27% in Fiscal Year 1985, 29% in Fiscal Year 1986, and 30% in Fiscal Year 1987. Although the Older Americans Act allows the Commissioner on Aging to determine the percentage of transfer between congregate and home-delivered meals, the Interim Final Regulations for the 1984 Amendments, published April 1, 1985, allow the States to transfer up to 30% between the two meals services without having to obtain the Commissioner's permission. We believe that these provisions give each State sufficient statutory and regulatory authority and flexibility to establish program emphasis which responds to the needs of its own over-75 population.

FUNDS FOR STATE ADMINISTRATION

Question. Can you estimate how much title III funding will be used by States for administration under the consolidated arrangement in Fiscal Year 1985?

Answer. We estimate that $30.5 million will be used in Fiscal Year 1985 for State Agency Activities.

FUNDS FOR SUPPORTIVE SERVICES

Question. Since funds for supportive services bolster the nutrition program, e.g., by providing transportation to meal sites, do you see a need to increase funding for the supportive services category more, as compared to the other components, so that the supportive service component may keep pace with increases in nutrition services?

Answer. We do not believe that there needs to be an increase in funding for supportive services to keep pace with the increases in the nutrition services program. Under current law, States may transfer funds between Titles III-B and III-C. These transferred funds can be used to increase meals directly or to provide additional supportive services that are appropriate to the provision of nutrition services such as transportation.

FOCUS OF PROGRAMS FOR THE DEVELOPMENTALLY DISABLED

Question. The 1984 amendments to the Developmental Disabilities Act added employment-related activities as a priority service area. As States move to implement this new priority, will services to the more severely handicapped, lower functioning persons be maintained?

Answer. Services to severely handicapped, lower functioning persons are not currently affected by the change in Public Law 98-527 which mandates employment related activities. This requirement does not take effect until fiscal year 1987 and is only one of a number of services that States may provide for persons with developmental disabilities. Furthermore, there is no minimum amount of funding required for employment related services. The States will continue to have significant flexibility in providing services that best meet the needs of all persons with developmental disabilities. Not less than 65 percent

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of the funds under the Basic State Grant Program must be expended on at least one but not more than two of the following services: alternative community living arrangements; employment related activities; child development; and case management. States may also provide other specialized services or special adaptations of generic services under the Basic State Grant Program. The other components of the Program complement the efforts of the Basic Support Program to establish a continuum of services, capable of meeting the changing needs of individuals with developmental disabilities throughout their lives. The University Affiliated Facilities, for example, are engaged in activities for children and elderly persons with developmental disabilities, in addition to focusing on services to adults with varying abilities. Similarly, the State Protection and Advocacy agencies serve individuals and families in a variety of ways to ensure the receipt of appropriate services.

ADMINISTRATION'S WORK INITIATIVE

Question. The Administration's supported work initiative places emphasis on disabled persons with employment potential. What guidance is the Administration on Developmental Disabilities providing to States regarding State responsibility to address the needs of all developmentally disabled persons, not only those with employment potential?

Answer. The Administration on Developmental Disabilities issued two program instructions to the States on the new requirements under Public Law 98-527. These program instructions provided guidance for the use of fiscal year 1985 funds and required the States to provide assurance and documentation of compliance with the new provisions of the law. In addition to these program instructions, which emphasize the comprehensive requirements of Public Law 98-527, the Department is planning to issue program regulations that will further clarify the broad focus of the Developmental Disabilities Program of promoting self-sufficiency for all persons with developmental disabilities.

STATUS OF INTERAGENCY COMMITTEE

Question. The 1984 amendments to the Developmental Disabilities Act required the establishment of an interagency committee to plan and coordinate activities conducted by the Federal Government for the developmentally disabled. Has this committee been established and, if so, what priorities is the committee addressing?

Answer. The Secretary of Health and Human Services appointed the Commissioner of the Administration on Developmental Disabilities, Jean K. Elder, Ph.D., as Co-chairperson of this Interagency Committee. The Secretary also sent a letter to the Secretary of Education asking for his designation of a Co-chairperson and other representatives to the Interagency Committee. This letter requested that the Secretary of Education cosign letters to be sent to the Secretary of Housing and Urban Development, the Secretary of Labor, the Attorney General, and the Chairperson of the National Council on the Handicapped, requesting

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that they designate their representatives to this Interagency Committee. The Department of Education has indicated that action on these joint letters is imminent. Preliminary work on the first meeting of the Interagency Committee is currently being done by staff of this Department and the Department of Education and the first meeting of the Interagency Committee is planned for the Spring of 1985.

RUNAWAY YOUTH PROGRAM

Question. Do you feel the three areas of inadequacy cited in the 1983 GAO Report in the Runaway Youth Program (after care services, outreach services, and activities to help youth learn coping and living skills) have been improved?

Answer. Yes. We do feel that improvements are being made in the areas cited by the 1983 GAO Report.

Question. If so, in what ways?

Answer. After funding 10 demonstration projects to develop models for training outreach workers for methods of provision of aftercare services and independent living skills, coordinated service networks able to utilize this information were developed. These networks have provided Statewide outreach, improved public and private involvement in aftercare, and improved the shelters' ability to counsel on living skills.

Question. What has the Department done to encourage improvement in these areas?

Answer. In addition to the actions described above, the GAO Report was disseminated to all shelters and regional offices. The Department has amended the performance standards to include outreach, aftercare, and management of leisure time components and made these areas part of monitoring reviews. We continue to highlight these areas in Research and Demonstration and monitoring activities.

SOCIAL SERVICES BLOCK GRANTS

Question. How many States have submitted their required biennial reports on activities under the Social Services Block Grant (SSBG) for FYs 1982 and 1983?

Answer. A total of 19 States have submitted their required reports for the biennial period of Fiscal Years 1982 and 1983. Twelve States sent post expenditure reports for only one year as follows: five for FY 1982, four for FY 1983 and four for 1984.

Question. Have you established deadlines for these reports?

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Answer. While we have not established deadlines for these reports, the Department plans to amend current regulations for all Departmental block grant programs. Included in that proposed rule may be a requirement for a deadline for post expenditure reports.

Question. Have you prescribed a uniform format for these reports to allow national comparisons?

Answer. We do not plan to require a uniform format, based on the Department's effort in the block grant program to provide flexibility to States where possible and the thrust of Executive Order 12372.

Question. Will you be publishing a summary of these reports?

Answer. We expect to prepare an analysis of the post-expenditure reports similar to the analysis that we have prepared for the pre-expenditure reports for the past three years.

Question. Pre-expenditure reports which have been submitted to the Federal Government have varied in format, preventing a complete national summary of these documents. Do you plan to require States to follow a uniform format for these reports?

Answer. Under the Block Grant statutes and the Department's regulations, each State has maximum latitude to determine the manner in which it will comply with the various statutory provisions. For this reason we do not intend to require States to follow a uniform format for the required reports as doing so would mean a loss of State flexibility in this regard.

Question. If not why not?

Answer. As stated in the answer to the preceeding question, we do not intend to require States to follow a uniform format for the required reports as doing so would mean a loss of State flexibility in this regard.

Question. Is it possible, from data which you have available so far, to provide any information on the number of participants in SSBG programs, and to break this number down by certain categories, such as age, handicapped status, and so on?

Answer. The statute does not require States to report this information and therefore it is not available except where some States have chosen to provide the information.

Question. Is it possible to provide information on the percentage of funds being used nationally for various types of services, such as child day care, home-based services, emergency services, etc.? If so, please submit these data. If not, please describe any plans you may have for obtaining this information.

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Answer. As I noted in the previous question, States are not required to provide this type of information. We have no plans to ask the States to submit this very specific type of data.

Question. Please describe your procedures for administering the $25 million in additional SSBG appropriations provided in FY 1985 for prevention of child abuse in day care centers.

Answer. On January 15, 1985 we published a notice in the Federal Register informing States of the additonal $25 million under the SSBG. This notice set forth the requirements States must meet by September 30, 1985. States must submit their documentation of compliance (implementing laws and regulations) by July 31, 1986. States that are not in compliance will have their SSBG funds reduced by one-half of the amount a State received under the $25 million allotment.

Question. What requirements do States have to meet and how will they be enforced?

Answer. The notice contains the following requirements: (1) These funds must be used only for the purpose of providing training, including training in the prevention child abuse in child care settings; (2) These funds must be expended only to supplement existing funds; (3) These funds must be separately accounted for in the reports and audits that are required for the SSBG. As provided in the legislation, the announcement tied the use of the additional $25 million to the enactment of State laws and regulations requiring nationwide criminal record checks for all employees and others in child care facilities, juvenile facilities, and other settings. Failure to do so by September 30, 1985 would result in the reduction of funds by one-half of the amount a State received under the $25 million allotment. To document compliance with this provision, States must submit copies of their implementing State laws and regulations.

Question. To what extent will these funds be coordinated with activities under the Child Abuse Prevention and Treatment Act?

Answer. In the notice, States have been encouraged to coordinate the expenditure of these funds with the State agency receiving State grants under the Child Abuse Prevention and Treatment Act.

Question. To what extent are States using non-SSBG funds to offset reductions in the Social Services Block Grant since FY 1981?

Answer. Recent studies by GAO and the Urban Institute show that State governments' own funds provided the principal scurce of replacement dollars to offset reductions in the SSBG since FY 1981.

Question. Do you have any information on State reaction to the budget reduction, such as differences in State

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priorities, eligibility criteria, increased use of fees, or elimination of certain services?

Answer. States shifted funding for some programs from the SSBG to other, open-ended Federal matching grants. Foster care services could be shifted to Title IV-B of the Social Security Act, child day care to Title IV-A (as an income disregard under AFDC) and home based services for the elderly to Title XIX, Medicaid. Most States when reducing spending on social service programs did so selectively, rather than making across-the-board reductions. In general, the highest priority was given to maintaining spending levels for crisis intervention services -- especially Child and Adult Protective Services. States chose to make the biggest program cuts in non-crisis services and administrative expenditures such as staff training, counseling, transportation and information and referral services.

Question. What effect have reductions since FY 1981 in related programs, such as community services activities and job training, had on the Social Services Block Grant?

Answer. An analysis of the information provided in the GAO studies and the Urban Institute reports does not address reductions in related programs having a major effect in the SSBG.

Question. Has competition for SSBG funds increased since FY 1981?

Answer. The GAO studies and Urban Institute reports note that the next few years will be pivotal ones as States and their constituencies debate how to set program priorities and allocate funds to meet recipent needs.

WORK INCENTIVE PROGRAM

Question. How is the Work Incentive (WIN) Program being coordinated with activities for welfare recipients under the Job Training Partnership Act? Are the two programs working as complementary to each other? For example, to what extent are welfare recipients enrolled in JTPA training programs having their child care costs funded through WIN?

Answer. States, in their State WIN plans for FY 1985, have indicated close cooperation between WIN and JTPA. Some States reported on written agreements detailing the scope of cooperation and projected outcomes. In addition, a January 1985 study entitled An Independent Sector Assessment of the Job Training Partnership Act, Phase II: Initial Implementation prepared by Grinker, Walker and Associates stated that of the 25 JTPA local service delivery areas studied, 13 had coordinated programs with welfare departments, including the WIN Program, which went beyond cross referral.

Question. What is the current status of WIN Demonstrations? How many States are currently administering demonstrations? Do

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you have any evaluations yet of what States are doing with their WIN Demonstration authority? Do you have any plans to publish evaluations in the near future?

Answer. The Supplemental Appropriations Act of 1984 extended the application period for WIN Demonstrations to June 30, 1985, allowed States with WIN Demonstrations approved before June 30, 1984 to continue to operate until June 30, 1987 and allowed States approved after June 30, 1984 to operate WIN Demonstrations for three years.

There are currently twenty-two (22) States operating WIN Demonstration Projects:

Arizona	Michigan
Arkansas	Nebraska
California	New Jersey
Delaware	Oklahoma
Florida	Oregon
Georgia	Pennsylvania
Illinois	South Dakota
Iowa	Texas
Maine	Virginia
Maryland	West Virginia
Massachusetts	Wisconsin

The Office of Family Assistance, Social Security Administration, is currently completing a first year evaluation of the WIN Demonstration Projects. It is anticipated that this report will be submitted to Congress within the next few weeks.

NATIONAL CENTER OF CHILD ABUSE AND NEGLECT

Question. How will the broadened mission of the Child Abuse Prevention and Treatment Act affect the work load and staffing at the National Center on Child Abuse and Neglect?

Answer. The National Center's role is developmental. Existing staff levels will be maintained. We have attempted to redefine our goals and objectives and to use staff and fiscal resources efficiently. We believe that we have been very successful in doing so.

Question. Will data on annual reported incidents of child abuse/neglect continue to be collected and published?

Answer. Yes, data on annual reported incidence of child abuse/neglect will continue to be collected and published.

Question. Who will be collecting and publishing this information?

Answer. The organization which will continue to collect and publish data will be determined through the Department's procurement process.

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HEAD START PROGRAM

Question. Head Start appropriations for FY 85 were increased by nearly $80 million over FY 84. How are these funds being used?

Answer. An increase of approximately $78.7 million is available in Fiscal Year 1985 for direct services to children. This increase will be used for three purposes:

(1) $33 million will be used to provide cost of living awards to current programs.

(2) $29.4 million will be used to expand Head Start services so that an additional 14,000 chilren can be enrolled in Head Start.

(3) $16.3 million will be used to improve the quality of services in current Hed Start programs.

Question. Does the Department anticipate again proposing to merge Head Start appropriations with the funds for the Child Care Food Program in the Head Start request for FY 86? What are the advantages of this approach when such a merger has not been supported by either Congress or Head Start associations in the past?

Answer. The Administration has no plans at this time to propose again the transfer of child care food funds from USDA to Head Start.

Question. Has the Department developed plans for training activities using the funds earmarked for that purpose in the 1984 reauthorization of Head Start (Human Services Reauthorization Act, P.L. 98-558)?

Answer. Plans for using the $25,000,000 earmarked for Head Start training and technical assistance have been developed and are being implemented.

The funds support several Head Start Training and Technical Assistance activities which include eighteen Resource Support Grants (RSGs), direct funding of 1,182 local grantees to manage and implement their own Training and Technical Assistance services, and support of national Training and Technical Assistance projects, such as the agreements with the Public Health Service and the Indian Health Services for Head Start dental services, training assessment for Child Development Associate credentials, and other projects of national significance.

Question. Has the Department developed new procedures for allocation of Head Start funds reflecting continued funding of existing agencies as long as they meet program and fiscal management standards as mandated under the 1984 reauthorization of Head Start?

Answer. The Department's procedures concerning the selection of Head Start agencies conform to the requirements of

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Section 641 of the Head Start Act, including the revisions to this Section enacted during the 1984 reauthorization. It has not been necessary to institute new procedures as a result of the 1984 reauthorization of Head Start. Priority for funding is given to current grantees.

TERMINATION OF THE COMMUNITY SERVICES BLOCK GRANT

Question. The Administration's budget calls for the termination of CSBG--Legal Services and the WIN program and suggests that states can fund each of these programs from SSBG. That would add almost one billion dollars more of activity to SSBG--more than one-third the SSBG appropriation. What incentives are being provided to states to direct funds away from the vital services already provided by SSBG to the new activities that these programs represent?

Answer. With respect to the Community Services Block Grant (CSBG), it is important to keep in mind the fact that a very large part of the CSBG allocation to the States is used not for programmatic activities uniquely funded from CSBG but for administrative overhead costs incurred by CAAs delivering programs supported from other Federal funding authorities, such as Head Start and LIHEAP. The Social Services Block Grant (SSBG), funded at $2.7 billion, is being asked, therefore, to absorb only a relatively small part of the $335 million CSBG budget.

The SSBG already funds some social services---such as child day care, family planning, health related services, home management information and referral, transportation and chore services--- which are identical with those funded in a number of states from the CSBG. Other CSBG activities, such as family and community gardening, are not currently supported by the SSBG but would, through our proposed amendment to the SSBG Act, become eligible for SSBG funding.

The elimination of the CSBG, will of course, require the States to reprioritize social services expenditures. Those CSBG services which are not funded will be, we believe, ones which States feel have lower priority or have not proven their effectiveness. By the same token, States can be expected to drop low priority SSBG activities in order to fund former CSBG activities which they believe have greater utility.

The elimination of the CSBG will serve as a stimulus to States not only to reprioritize social services expenditures but to streamline the entire social services delivery system. According to a report published in 1983 by the National Governors' Association (NGA): "It is a misnomer to speak of a human services system. The enormous, costly effort to provide services to individuals is actually a patchwork of activities involving many different governmental agencies at the Federal, state and local level. There is enormous duplication of services and widespread inefficiency in the system, along with a failure to produce the results expected. Thankfully there is decreasing emphasis on single-purpose, categorical programs and increasing emphasis on flexible multi-purpose programs which can deal with human service needs in a more comprehensive way". The absorption of CSBG activities into the SSBG, one of the most flexible of the nine block grants created by the Omnibus Budget and Reconciliation Act of 1981, along with the streamlining of the social services delivery system that should result from elimination of the CSBG, can

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be expected to produce savings, some of which could be used to continue those CSBG activities considered high priority.

In addition, states and localities have the option of supplementing SSBG funds from their own treasuries. State and local governments are by and large in much better financial shape than the federal government and thus better able to absorb the costs of social services not already included within the vast array of federal programs---totaling $68 billion---which constitute the basic "safety net" for poor people. Forty eight of the fifty states registered a surplus of $6.3 billion in FY 1984. A surplus of $5.3 billion is projected for FY 1985. In addition, local governments recorded surpluses for every year in the 1980-83 period: $2.2 billion in 1980; $5.4 billion in 1981; $6.2 billion in 1982 and $4.1 billion in 1983.

Question. What percentage of these three programs--WIN, Legal Services and CSBG--do you envision states reallocating SSBG to cover?

Answer. With respect to the CSBG, the decision on whether to reallocate SSBG funds for CSBG activities and on the percentage of such funds to be reallocated would have to be made by each State, depending on a particular State's social services needs and priorities. Since the relative urgency of various social services needs varies from State to State, it is not possible, at the Federal level, to generalize on what percentage of SSBG funds the States might or should adopt.

Question. What research has your office done on this subject?

Answer. For the reasons given in the answer to the previous question, we have done no research on this subject.

Question. You say that states fund the same kinds of activities with both SSBG and CSBG. Could you list for us some of the duplicative programs?

Answer. We are not contending that the specific activities fumded under the SSBG are identical with those funded under the CSBG, although there is some overlap among these activities. For example, the State of Iowa, in a letter to OCS written in December, 1983 lists the following activities that are funded from both the SSBG and CSBG: volunteers, child day care, family planning, health related services, home managment information and referral, transportation and chore services. Despite this overlap, it is conceded that most of the specific activities now funded under the SSBG differ from those funded under the CSBG. However, there is clear duplication between the two block grants in the sense that: (1) both these block grants have as one of their principal purposes the delivery of "human" and "social" services; (2) both block grants serve essentially the same population ---people who are indigent or who have little income; (3) both block grants have in common the goal of decreasing dependence on public assistance and encouraging self-sufficiency; and (4) in order to carry out these two essentially similar programs, there are two sets of regulations and requirements at both the state and Federal level along with two administrative apparatuses at the Federal level, and in many cases, at the state level.

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Question. The priority programs of SSBG are day care and protective services for the abused and other vulnerable people. What percentage of CSBG funds are being used for these programs?

Answer. We have no figures on the percentage of CSBG funds that are being used for abused and vulnerable people. We do know however, that a number of community action agencies use CSBG funds for day care and for services for the abused. In a National Governor's Association (NGA) report issued in November, 1984 a list of the specific services provided under the CSBG included "day care and child development services" and "intervention services in instances of child and spouse abuse."

Question. Can you please provide for the record any studies your office has done on duplication of programs within the same jurisdictions?

Answer. We have done no studies on the duplication of programs operated, for example, by the SSBG and CSBG since our claim of duplication between these two block grants is not based on overlap of specific services (see answer to the first question above). Nonpartisan studies of social service programs at the State level confirm the fact that there is considerable duplication of programs and that there is a need to consolidate many of these programs. According to an NGA report in August, 1983: "Studies indicate that expenditures for human services comprise 51% of the Federal domestic budget and some 63% of aggregate state budgets. Yet, it is a misnomer to speak of a human services system. The enormous, costly effort to provide services to individuals is actually a patchwork of activities involving many different governmental agencies at the Federal, state and local level, as well as a wide array of private agencies and nonprofit corporations. No single governmental or private authority supervises or reviews this vast and complex process. As a result, there is enormous duplication of services and widespread inefficiency in the system, along with a failure to produce the results expected of the system."

Question. What is the source of your information that CSBG is used chiefly to cover the costs of administering other programs? The National Governors' Association study that you cite says that CSBG funds generate other dollars but does not give a breakdown on the use of CSBG funds otherwise. Can you provide any studies your office has done on the uses of CSBG funds?

Answer. It has been commonly accepted over the years that funds supplied to the CAAs by the Federal government have been used, for the most part, to pay CAA staff, rent, utilities and operation costs. In November, 1983, the NGA referred to the "tradition established by the Office of Economic Opportunity (OEO) and continued by the Community Services Administration (CSA), of using federal anti-poverty funds to provide core administrative staff to accept and operate Head Start, weatherization, cheese distribution, community development and other programs." A year later, in another report referring to the CSBG Program, the National Governors' Association (NGA) spoke of the "traditional practice of using community services funds to finance core staff who plan, mobilize and administer a variety of public and private services for the poor."

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According to a recent survey by the National Community Action Foundation (NCAF), only 20% of the CSBG appropriation is used by CAAs to supplement the administrative costs of other federal programs operated by CAAs, e.g., Head Start, Older Americans programs, low-income energy programs, commodities distribution and others. However, the NCAF report also states that another 20% of CSBG funds are used by CAAs for the "management of CAA programs" i.e., for such things as central fiscal management, community-wide needs assessment and planning, mobilization of resources, volunteer recruitments etc. Since all of these activities are integrally connected to the $2.4 billion array of other Federal programs operated by CAAs, the CSBG contribution to the administrative costs for these programs can reasonably be assumed to be considerably more than 20%.

Other studies of the CSBG would seem to support this assumption. A General Accounting Office (GAO) report on the CSBG issued in August, 1984, states that the amount of CSBG funds used to pay administrative costs of other programs varied from "2 percent at one provider to 100% at three others." "Fifteen (providers)," the report continued, "used at least 25% of their funds to administer other programs such Head Start and the Emergency Food Assistance Program. For example, Self-Help, Inc., in Brockton, Massachusetts said at least 80 percent of its CSBG funds were used to administer other programs" while " West Central Development Corporation in Harlan, Iowa...used almost all [illegible] CSBG funds to support other federal programs..."

Question. You say that states use SSBG and CSBG funds for the same activities and then that CSBG is used for the administrative support of other programs. Is that what your understanding of SSBG use is?

Answer. Our position is that a very large portion of the CSBG appropriation is used to supplement the administrative monies provided under other Federal funding authorities for other Federal programs. There is no duplication between this use of CSBG funds and the uses to which SSBG monies are put. We believe, however, that the portion of CSBG funds which is used for direct services, as distinct from administration, is duplicative of the SSBG in the sense that they are for the same generic kinds of services ("social" services or "human" services), are targeted on basically the same population (low income persons) and have the same purpose--to assist people to become self-sufficient.

Question. I have here a survey done on the use of CSBG funds by community action agencies which was conducted last year by the National Community Action Foundation. The administrative category is the smallest expenditure category. Community action wide management activities is the next smallest and provision of direct program services equals 60%.

Answer. The question of the percentage of CSBG funds used for administrative costs has been addressed in the answers to the previous two questions. With respect to the NCAF figure of 60% for direct services, some of the services listed as "CSBG-type" programs, that is, programs supported exclusively from CSBG funds, are in fact the kinds of programs which are heavily supported, even when operated by CAAs, from funds provided by agencies other than OCS. For example, CAAs are

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extensively involved in economic development activities funded from HUD's $3.1 billion economic development block grant. Similarly, programs for the homeless, far from being exclusively "CSBG-type" programs, have been supported (even when operated by CAAs) from funds and foodstuffs provided by HUD, FEMA and USDA. In an NGA study prepared in November, 1984, it is noted that "fully half of the state governors picked their CSBG offices to administer the Emergency Food and Shelter program established by the Jobs Bill." But the program funds used for this effort were not CSBG program funds. They were funds provided by FEMA.

Question. You say the administrative funds of a CAA are used to support federal programs. What funds are used for the administrative funds for CSBG programs themselves and local, state and private programs generated by CAAs?

Answer. The NCAF study suggests that upwards of 20% of CSBG funds are used to administer programs other than the $2.4 billion array of Federal programs which constitute the major part of the CAA operation. We have no figures on the exact amount of CSBG funds which are used to administer local, state and private programs but it should be noted that these programs represent only a fraction of the CAAs budget. According to a study done by the NGA in November, 1983, the private sector contributed 1.3% to the total CAA budget while state and local governments contributed .05%.

Question. The NGA study lists numbers of programs operated by CAAs from CSBG funds as does the NCAF survey. What percentage of CSBG funds are used for direct program services to the poor?

Answer. According to the NCAF survey, 60% of CSBG funds are used for direct services to the poor. We can find no independent support for this figure. As indicated in our answer to a previous question, a number of the activities listed by NCAF as direct services supported by the CSBG include services provided under other Federal programs. The NGA studies list all the activities conducted by CAAs but there is no clear demarcation between the activities supported solely from the CSBG and activities supported from the $2.4 billion received by the CAAs from other Federal programs. The problem of disentangling CSBG-supported services from other federally-supported services provided by CAAs is similar to the problem of sorting out administrative costs. This problem was noted by the GAO in a report on the CSBG prepared in August, 1984.

According to the GAO report: "The direct link between CSBG and providers' services and clients is obscured in many locations because block grant funds are used to pay the costs of administering other programs...For example, Self-Help, Inc., in Brockton, Massachusetts said about 80 percent of its CSBG funds were used to administer other programs and, as a result, funding changes (in the CSBG) could not be translated into service changes (i.e. changes in amount of direct services provided under the CSBG)" (Parentheses added). Elsewhere in its report, GAO made the same point as follows: "Discerning the exact impact of the block grant was often difficult because many providers used federal community services funds to administer other programs and the link between CSBG funding decreases and program changes were obscure." On the basis of the scant evidence that is available, and the known pattern of the CAAs historical use of federal funds provided by OEO and CSA for administration costs, it would ap-

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pear that the NCAF estimate that 60% of CSBG funds are used for direct services is too high.

Question. You say there is no difference between the statutory purposes, the kinds of activities and the clientele of SSBG and CSBG. Would you please outline for us the statutory purposes, describe the clientele and give us a brief listing of the programs under these two programs, Dr. Vieth, so that we can understand how you've arrived at what I view as an erroneous conclusion?

Answer. The populations served by the two block grants, though not identical, largely overlap. Under both grants, services are provided to low income people. With respect to the services delivered, we are not suggesting that the specific services provided under the two block grants are identical, although in some cases these do overlap (as in the case of child day care services). We are claiming, rather, that the various services authorized under the CSBG and the SSBG Acts are identical in kind: they are all "social services" or "human services".

Differences in intent and purpose between the SSBG and CSBG are more apparent than real. As noted in the opening statement, historically the community action agencies were supposed to "focus resources on the goal of enabling low-income people to become fully self-sufficient". But two of the five goals of the SSBG also relate to the achievement of self-sufficiency by poor people. The CSBG Act speaks of ameliorating the causes of poverty while the SSBG Act seeks to prevent dependency. Dependency is a consequence of poverty. To combat one is to combat the other. To make explicit the link between poverty and dependency and to insure that States will have the authority to use SSBG funds for CSBG-type activities, the Department has proposed amending the SSBG Act to add "alleviate poverty" to the purposes section of the Act.

The SSBG is operated mainly through county welfare offices while the CSBG is operated mainly through community action agencies. But the differences are not so pronounced as to justify two separate block grants. SSBG funds can be used by county welfare offices to subcontract for services from community action agencies. As a matter of fact many county welfare offices are now using community action agencies to deliver such SSBG-funded services as child care services, family planning services, and home management information and referral services.

The problem of costly duplication of social services delivery systems at the State and local level was noted by the Institute for Local Self-Government (ILSG) in its report on the CSBG in June 1982. The Institute commented: "The human services system in most States is a patchwork of categorical programs, block grant programs and combinations of the two. The way the system has developed over seventeen years has created problems of several programs providing the same services, clients that must receive basic services from as many as five or more different programs and certain need populations that receive no service at all."

The movement to consolidate social services delivery systems is well underway at the State level. For example, a January 1982 report on the SSBG by the American Public Welfare Association notes that "Kentucky and Massachusetts are looking at ways to eliminate

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duplication of services provided under Title XX (now the Social Services Block Grant) and under the Community Services Block Grant". (Parenthesis added). We believe that in the interest of economy, efficiency and greater flexibility for the States, Congress should pursue the idea announced in the first sentence of the SSBG Act and merge the two block grants. The first sentence of the Act reads, in part: "For the purposes of consolidating Federal assistance to states for social services into a single grant...".

We further believe that Congress did not necessarily intend the two block grants to complement each other. The creation of the two blocks was largely due to the fact that many different committees were involved in the preparation of the Omnibus Reconciliation Act of 1981 (OBRA). In the process of creating the OBRA, the House did, in fact, pass a Social Services Block Grant which included the Community Services program, as the Administration had proposed. Because of committee jurisdictions, the CSBG and the SSBG were taken up in separate conference actions, resulting in the inclusion of both programs in the OBRA.

CSBG PROGRAM STUDIES

Question. What studies has your office done on the impact of CSBG programs?

Answer. The Office of Community Services has not done any studies on the impact of CSBG programs. We believe that States are responsible for evaluating the impact of the CSBG program as part of their management responsibility for the CSBG program.

However, OCS is statutorily required to insure that States are complying with a variety of statutory assurances. Each year ten States plus one territory are visited by OCS personnel to insure compliance with these statutory requirements. Consonant with the 1984 revision in the CSBG legislation, the reports from the on-site visits will be supplied to the Congress at the end of each fiscal year.

Question. What have you done to support these programs and to promote them?

Answer. The OCS supports the CSBG program by ensuring that:

1) grant awards are made in a timely manner,
2) State requests for assistance are responded to expeditiously,
3) IO program implementation assessments that include findings and recommendations are done annually,
4) funding is provided to the Center for Local and Community Research to assist the States in the collection of FY 1984 CSBG program information through the "National Voluntary Reporting System" project.

TRAINING AND TECHNICAL ASSISTANCE

Question. Is there a strategy in OCS to assist CSBG grantees to get private funding to replace lost federal funding?

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Answer. OCS has no formal strategy to assist CSBG grantees to get private funding to replace lost federal funding.

We believe the primary responsibility for assisting CAAs in their anti-poverty activities, including the mobilization of private sector resources, rests with the States. As was noted in the conference report for the Omnibus Budget and Reconciliation Act (OBRA) of 1981: "The (CSBG) Act places greatly increased responsibilities on State governments to design and administer effective programs...for a variety of specific...purposes". Among these purposes is that of encouraging "the use of entities in the private sector of the community in efforts to ameliorate poverty in the community."

States should also be in a better position than in the past to use State resources toward this end. According to a report published in February, 1985, by the National Association of State Budget Officers: "The nation's states ended fiscal year 1984 with a balance of about $6.3 billion. Estimates for fiscal year 1985 place the ending general fund balance at about $5.3 billion. These levels are a welcome turnaround from the historically low year-end balance of $2 billion in fiscal year 1983."

In addition, one of the principal tools which community action agencie have been enjoined by Congress to use during the past twenty years in the effort to eliminate poverty has been the mobilization of private sector resources. Hundreds of thousands of Federal dollars have been expended over the years by CAAs in perfecting this tool, and in developing innovative strategies for its successful use. We assume that these expenditures have not been in vain, and that the CAAs have developed the expertise needed to search out private sector dollars to replace CSBG funds.

Question. Are you providing training and technical assistance to states and local programs?

Answer. The OCS staff provides training and technical assistance to States in a variety of ways:

1) respond directly to State requests for information or assistance,
2) attend regional and/or State meetings of State CSBG program officials to discuss issues of concern to State administrators,
3) work with States at time of submission of annual application and program implementation on-site visits.

OCS does not provide direct funding to States for training and technical assistance because we believe that States which desire training and technical assistance have the capability to obtain it with a portion of their CSBG administrative funds or other State resources. OCS does not provide assistance to local programs.

AMENDMENTS TO THE CSBG ACT

Question. For that matter, the amendments to the Community Services Block Grant legislation were passed in early October 1984. What guidance have you sent to the states on implementing them and when was it sent? (See attached letter from Jane Checkan dated Jan-

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uary 24, 1985--first communication states got on this subject--WHY SO LONG?)

Answer. States were first notified of the applicability of the amendments to the CSBG program in the letter to the Governors notifying the States that their FY 1985 application had been accepted by OCS. This letter was mailed to all States with accepted applications on November 2, 1984 and as State applications were accepted after that date, each State was notified.

In the January 24, 1985 letter from Mrs. Checkan, States were sent copies of the Public Laws 98-619 and 98-558 and the amendments relevant to the CSBG statute were identified.

On February 14, 1985, each Governor was sent a letter signed by Dr. Vieth which requested States to comply with the amendment which added a new assurance to those already made by the Governor in the FY 1985 application. This letter also included a copy of the Human Services Reauthorization Act of 1984. (Copies of all letters are attached.)

The Department is completing its regulation governing implementation of the amendments to the block grant statutes and this regulation should be published in the near future.

DIFFERENCES BETWEEN THE SSBG AND CSBG

Question. Your office gets the CSBG plans and reports. Don't they show that most states have to certify to their legislature that CSBG is not being used to duplicate other programs in the same jurisdictions?

Answer. The reports from some States do show that there has been no duplication in the specific services provided under the CSBG and under other funding authorities such as the SSBG. In other States, such as Iowa, the same specific services such as day care and child care services are provided under both block grants. However, this is not the type of duplication we have in mind in arguing for repeal of the CSBG. As stated in our answer to an earlier question, the CSBG and the SSBG are duplicative with respect to the broad kinds of services (social services) authorized to largely the same low-income population for basically the same purpose: the achievement of self-sufficiency. In addition, there is duplication between the administrative funds taken from the CSBG to help deliver other Federal programs and the administrative funds already available under the funding authorities for these programs.

Question. First you say the SSBG and CSBG block grants are essentially the same, then you state there are differences. Could you list for us the activities that are funded under CSBG that are not identical to those of SSBG?

Answer. As indicated in our previous answer, we are not contending that there is any substantial duplication between the specific activities that are funded under the SSBG and the CSBG. Typically, SSBG funds are used for: adoption, adult day care, adult protection, child protection, court-ordered client oversight, foster care, family planning, health related services, home management information and referral, transportation and chore services. (In some

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states, CSBG funds are used for some of these activities, such as child day care and home management information and referral.)

Typically, CSBG funds are used for such thing as summer youth employment, workshops for the unemployed, economic development, congregate meals, food pantries, cheese distribution, food stamp outreach, community and family gardens, housing rehabilitation, tenant/landlord workshops, health screening, rent and mortgage crisis loans and grants, etc. A portion of CSBG funds is used for advocacy, central fiscal managment, leveraging private sector resources, and planning and coordinating the various anti-poverty programs. Another portion of CSBG funds is used for supplementing the administrative monies provided to CAAs by other Federal agencies which use CAAs to deliver their programs.

Question. What will happen to those activities if CSBG is terminated?

Answer. Most of the activities funded through the CSBG are conducted by community action agencies (CAAs). We believe that a majority of the CAAs will survive if the CSBG is terminated. As we have pointed out on a number of occasions, roughly 85% of the funding support for CAAs derives from Federal funding authorities other than the CSBG, such as the Head Start Program, the Low Income Home Energy Assistance Program, etc. Only 12% of CAA funds, on average, are supplied by the CSBG. Additionally much of this 12% is used for administrative overhead incident to the delivery of other Federal programs. The balance of the CSBG portion of the CAAs' budgets is used for activities of the type described in the answer to the previous question.

The Department has proposed an amendment to the Social Services Block Grant (SSBG) Act under which States could use SSBG funds to support many of the activities now funded from the CSBG. We realize, of course, that although we are requesting the full authorization amount of $2.7 billion for the SSBG in FY 1986, this may not be sufficient to fund all of the activities which were funded separately in FY 1985 under the CSBG and SSBG. States will have the option of continuing to fund CSBG activities which have demonstrated effectiveness. Those CSBG services which are not funded will be, we believe, ones which States feel have lower priority or have not proven their effectiveness. In these time of fiscal constraint, States can be expected to drop low priority SSBG activities in order to fund former CSBG activities which they believe have greater utility. In effect, we are giving States greater latitude to structure a continuum of services according to the particular needs of their own residents. Currently, most States have little flexibility to allocate funds in line with their unique needs since under the CSBG, they must pass 90 percent of CSBG funds through to existing grantees.

Question. Under what office personnel ceiling is the staff of the homeless task force currently charged?

Answer. The Homeless Task Force support staff of 6 employees is accounted for within the Department's Full-Time-Equivalent (FTE) ceiling.

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Question. Dr. Vieth, what incentives have you provided to states to fund CAAs under other block grants? Can you provide examples for the record?

Answer. The Office of Community Services believes that if the CAAs are an effective delivery system States will use them to deliver the services provided for in other block grant programs. OCS also believes in the concept of block grants that provides States the flexibility to determine themselves how to administer the CSBG program as long as their activities are in compliance with the statute. Therefore, we do not think incentives are necessary.

Question. Congress may be considering legislation for the homeless. Should that program be housed in OCS and have CAAs deliver the services?

Answer. Given the urgency of the need to reduce the Federal deficit through curbs on domestic spending, the Administration is opposed to any new Federally-financed program for the homeless. The Administration's FY 1986 budget request includes $68 billion for "safety net" programs, for which most homeless persons qualify. What is needed is a better targeting of these existing programs on the homeless. Beyond this, the federal role should be limited to catalyzing state and local government and private sector assistance for the homeless.

Question. How many people are there currently on the OCS staff?

Answer. There are currently 60 employees on the OCS staff. 54 employees are associated with the administration of the CSBG; and 6 employees are assigned to the Homeless Task Force support staff.

Question. The conference agreement on the continuing resolution for FY 1984 provided for 70 full-time equivalent slots for the federal administration of the Community Services Block Grant. Why haven't you maintained that level?

Answer. The OCS conducted a Reduction-in-Force (RIF) on September 30, 1983. All regional employees were separated and the national office was reduced to 53 employees. The continuing resolution provided $4,300,000 for administration to cover costs of salaries, benefits, travel and overhead expenses of those 55 employees plus severance pay and unemployment costs of employees separated on September 30, 1983.

Question. Dr. Vieth, do you think you should continue to direct the Office of Community Services when you spend so much of your time on the homeless task force and the only work you appear to do for CSBG is to advocate for its demise?

Answer. As Director of the Office of Community Services I manage and supervise 53 highly paid professionals to implement the CSBG Act, the Rural Development Loan Fund, the Community Development Credit Union Loan Fund and the Discretionary program.

The Homeless Task Force does not interfere with the management of the Office of Community Services.

As part of the budget process it is my responsibility to report the findings of the analyses of the program. In these hearings I am

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reporting statistical facts that only 12% of the total funding of the CAAs is represented by the CSBG. This is a fact that should be of interest to the Congress in these times of high deficits.

Question. How many Community Action Agencies are there currently across the country?

Answer. According to a National Governors' Association report, there are 861 community action agencies nationwide.

Question. How many people are being served by the Community Action Agencies?

Answer. States are not required to report to OCS the number of people served by the community action agencies funded by the States.

Community action agencies receive funds from a wide variety of federal, State and local governmental, as well private sector sources, in addition to the CSBG funds. Therefore, we would not be able to estimate a service population served by these nonCSBG funds.

Question. Dr. Vieth, you are head of the Intergovernmental Task Force on the Homeless. How much of your time does that take up and how does it fit with your duties as Director of the Office of Community Services?

Answer. There is no conflict between the Homeless Task Force and the management of the Office of Community Services. I have highly paid professionals working in both areas and I am confident that both are managed in an efficient, cost effective manner.

I spend the necessary time to manage both but do not log the percentage of time for either.

Question. How many staff people are available to the task force and to what office ceiling are they charged?

Answer. There are currently 6 support staff employees available to the Homeless Task Force. The staff is accounted for within the Department's Full-Time Equivalent (FTE) ceiling.

Question. From what budget are travel and meeting expenses of the non-government members of the task force paid?

Answer. There are no non-government members of the Homeless Task Force.

Question. How many grantees were added to the number of eligible entities because grantees in what were formerly the waiver states were included as eligible entitles in 1984?

Answer. The following are the waiver States and the number of grantees added to the number of eligible entities as a result of Section 202 (a)(1) of the Human Services Reauthorization Act of 1984 (Public Law 98-558): Colorado 14, Utah 3, and Wyoming 16, for a total of 33 grantees.

Question. The 1984 amendments authorize funding under the discretionary fund for training and technical assistance to states to

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aid them in carrying out the CSBG. Is it HHS' intention to fund a grant or contract in this area?

Answer. The 1984 amendments authorize a training and technical assistance category within the discretionary program for States to aid them in carrying out the CSBG.

Although training and technical assistance is an authorized activity, no funds were appropriated by the Congress for this activity in FY 1985.

We believe that States which desire training and technical assistance have the capability to obtain it with a portion of their CSBG administrative funds or other State resources.

Thus, we did not include training and technical assistance to States in the FY 1985 Discretionary Program.

Question. The federal government has retained an office to focus on the needs of the aged, the handicapped, veterans, refugees, and others. Why does the Administration want so badly to abolish any federal focus on the more than 35 million of our citizens who are in poverty?

Answer. The Administration's budget request for FY 1986 includes $68 billion for programs making up the so-called "social safety net". Each of these programs focuses either on a particular segment of the poverty population (e.g. the aged, women, infants and children, etc.) or on a particular need shared by the various sub-groups of the poverty population (the food stamp program, medicaid, etc.). The elimination of the CSBG would not abolish a Federal focus on poverty, but an unneeded duplication of this focus.

Question. You have figures at the end of your testimony that show the highest allowable overhead rates for several federal programs. These rates, of course, don't apply in all cases so the percentages received by CAAs are often much less. If CAAs were to pay their full share of overhead in the absence of CSBG, wouldn't they have to take that money from program funds?

Answer. We are not aware of any data that would support the theory that use of CSBG funds to supplement the administrative monies available under other Federal programs frees up funds for the expansion of program services.

It is noteworthy that CAAs, which once delivered 60 to 70% of Head Start programs, now deliver only 55% of these programs, serving approximately 42% of all Head Start enrollees. This decline is difficult to reconcile with the claim that the presence of CSBG funds reduces the administrative overhead in Head Start programs. In fact, the Head Start program frequently makes use of providers other than CAAs to deliver the same services at least as efficiently and sometimes at less cost, without the benefit of CSBG funds.

In any event, we believe that Congress, in authorizing program and administrative monies for Head Start and the other Federal programs mentioned at the end of my testimony, did not assume a CSBG offset for administrative costs, and provided sufficient program funds to carry out these statutes.

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COMMUNITY FOOD AND NUTRITION PROGRAM

Question. The Physician's Task Force on Hunger in America just released a report which found that "Hunger in America is a national health epidemic...available evidence indicated that up to 20,000,000 citizens may be hungry at least some period of time each month."

According to the Connecticut Association for Human Services, as of October, 1983 (the most recent data), only 1% of Connecticut children participating in the School Lunch Program also participate in the School Breakfast Program, despite the entitlement status of both programs. New Haven, for example, is the seventh poorest city in the United States but has no School Breakfast Program.

In light of these findings, why is the administration not recommending a fiscal year 1986 appropriation for the Community Food and Nutrition Program ...just authorized last year at a very modest $2.5 million and targeted on expanding participation in the Child Nutrition programs?

Answer. The Administration has not requested an appropriation for the Community Food and Nutrition Program (CFNP) for Fiscal Year 1986 because the CFNP is a part of the CSBG Act, as amended, which the Administration is seeking to have repealed.

In this period of increased employment opportunities and high deficits, another federally-funded food assistance program is not warranted. In Fiscal Year 1984, the cost of the present array of such programs---the food stamp, WIC, child care, school lunch, school breakfast and commodity distribtution programs---will have exceeded $19 billion. When compared with 1980, this represents a 36% increase in nominal expenditures and a 15% increase in real expenditures, (i.e., expenditures deflated by the 1980 and 1983 Consumer Price Indices for food at home).

For Fiscal Year 1986, the Administration is requesting additional increases in most food distribution programs, or a total increase of $250 million in food expenditures.

The $20 billion array of food assistance programs will be applied in Fiscal Year 1986 directly to the problems of hunger and malnutrition among the poor. The CFNP, on the other hand, if funded, would be used to encourage the proliferation of advocacy activities benefitting mostly the staffs of special interest organizations.

Question. Does OCS currently administer any community services programs which require that funds be expended to improve utilization of the Child Nutrition Programs and to improve emergency feeding efforts?

Answer. No. OCS does not administer any CSBG programs which require that funds be expended for Child Nutrition and to improve emergency feeding efforts. States are left as much flexibility as possible to establish their own priorities as to what programs will best help the poor and low-income. However, the statute does require that a State's Chief Executive Officer certify that the State will use its CSBG funds to obtain emergency assistance to meet immediate and urgent individual and family needs including the need for nutritious food.

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COMMUNITY SERVICES BLOCK GRANTS

Question. Does the Office of Community Services gather any data that would indicate the number of individuals served through the Community Services Block Grant (CSBG) or the types of services provided? If so, please describe this information. If not, please describe any plans for collecting this type of information.

Answer. OCS does not gather any data that would indicate the number of individuals served through the CSBG or the types of services provided.

As part of our support to States in their administration of the CSBG program, we provide funding to the Center for Local and Community Research in Berkeley, California. The purpose of grant is to assist the States to design and implement a National Voluntary Reporting System (NVRS) to collect information on FY 1984 CSBG operations in the 57 States and territories.

The NVRS collects information on the 7 major CSBG categories of services funded by the States, which include employment, education, better use of available income, housing, emergency services, nutrition, and linkages with other programs.

Question. The General Accounting Office recently reviewed CSBG operations in 13 States and found that States generally have not offset the reduction in funding for community services activities since FY 1981 with their own funds. What has been the impact of this funding reduction on local grantees, participants and the quality of programs?

Answer. The OCS does not collect data on program impact; therefore we are unable to determine the impact of the funding reduction on local grantees, program participants and program quality.

Question. Is the current size of the Office of Community Services adequate to monitor and oversee the Community Services Block Grant program?

Answer. Yes. The current size of the Office of Community Services is adequate to monitor and oversee the CSBG program.

Question. What, if any, technical assistance or program guidance is provided to local grantees by the Federal Government?

Answer. OCS does not provide technical assistance or program guidance to local grantees of CSBG funds. The States have the primary responsibility for providing the technical assistance and program guidance to their local grantees. Such activities are part of the States' management and oversight responsibilities.

DISCRETIONARY GRANTS

Question. How does the Office of Community Services monitor and oversee national discretionary grants?

Answer. The OCS monitors and oversees national discretionary grants through:

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1. Telephone conversations and written correspondence with grantees on matters of policy, HHS/OCS regulations, program and/or budget modifications, and compliance with grant general and special grant conditions.

2. Field monitoring visits to between 30% and 50% of each fiscal year's group of grantees (in FY 1984 there were 78 discretionary grants made by OCS).

3. Review of discretionary grantee quarterly narrative program progress and finacial reports to determine what progress is occurring in relation to the OCS approved work program and goals and to ascertain that grantees are expending grant funds in accordance with their OCS approved budget and grant program.

Question. What procedures are established to evaluate the effectiveness of national discretionary activities?

Answer. Each OCS discretionary program grantee is required to submit a final narrative program progress report which provides information on how well the grantee has performed and the extent to which the grantee has accomplished the OCS approved project goals.

Each OCS discretionary program applicant is advised in the Discretionary Program announcement that, "All proposals should include a self-evaluation component. The evaluation data collection and analysis procedures should be specifically oriented to assess the degree to which the stated goals and objectives are achieved. Qualitative and quantitative measures reflective of the scheduling and task delineation in (1) above '...Program Implementation...' should be used to the maximum extent possible. This component should indicate the ways in which the potential grantee would integrate qualitative and quantitative measures of accomplishment and specific data into its final program progress reports that are required by OCS from all grantees."

Applicants must essentially meet this application requirement and final program progress reports are supposed to reflect grantee evaluation plans.

COMMUNITY FOOD AND NUTRITION PROGRAM

Question. If Congress decides to appropriate funds for the Community Food and Nutrition Program which has recently been added to the CSBG authorizing legislation, how would you propose to administer such a program?

Answer. The OCS would provide funding to the types of agencies, and for the purposes, outlined in the legislation.

RURAL DEVELOPMENT LOAN FUND

Question. What is the current status of remaining funds in the Rural Development Loan Fund? Have these funds been used for rural development purposes, as directed by this Committee in its FY 1985 appropriations bill report? How much money, if any, remains in the fund?

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Answer. There is approximately $12.5 million in the Rural Development Loan Fund which the Department has proposed to transfer to the Family Social Services account for use in foster care and adoption assistance programs.

DUPLICATION OF SERVICES BETWEEN BLOCK GRANTS

Question. What percentage of Community Service Block Grant funds are used for these same services?

Answer. We have no figures on the percentage of CSBG funds that are being used for abused and vulnerable people. We do know however, that a number of community action agencies use CSBG funds for day care and for services for the abused. In a National Governors Association (NGA) report issued in November, 1984, a list of the specific services provided under the CSBG included "day care and child development services" and "intervention services in instances of child and spouse abuse."

Question. Would you please provide this committee with the data that supports your contention that repeal of the CSBG Act "should pose no threat to the continued existence of effective CAAs"?

Answer. It is quite possible that some CAAs, particularly those which have not been effective in the past in mobilizing non-Federal support, may have to suspend operations. However, we believe that a majority of the CAAs will survive if the CSBG is terminated. However, we believe that a majority of the CAAs will survive if the CSBG is terminated. As we have pointed out on a number of occasions, roughly 85% of the funding support for CAAs derives from Federal funding authorities other than the CSBG, such as the Head Start Program, the Low Income Home Energy Assistance Program, etc. Only 12% of CAA funds are supplied by the CSBG. In addition, much of this 12% is used for administrative overhead incident to the delivery of the other Federal programs mentioned above. This means that a relatively small portion of the total range of activities conducted by CAAs will be affected by termination of the CSBG.

Possible sources of funding support for such activities, where they are deemed by the States to be of high priority include: (1) the Social Services Block Grant; (2) savings which the elimination of the CSBG can be expected to produce through consolidation and streamlining of social service delivery systems at the State level; (3) surpluses in State treasuries (projected to be $5.3 billion in FY 1985); and (4) private sector resources..

Question. Why is it that the only network this Administration is trying to destroy is the one for the poor?

Answer. The Administration's budget request for Fiscal Year 1986 includes $68 billion for programs making up the "social safety net". Each of these programs is targeted either to a particular segment of the poverty population (e.g. the aged, women, infants and children, etc.) or to a particular need common to the poverty population (the food stamp program, medicaid, etc.). The elimination of the CSBG would not abolish a Federal focus on poverty but an unneeded duplication of this focus. In addition, since the CSBG constitutes only 12% of the budget of the CAA network which now

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receives most of the CSBG funds, we believe that the elimination of the CSBG would leave the CAA network essentially intact.

RURAL DEVELOPMENT LOAN FUND

Question. Why are you once again ignoring Appropriations Committee report language accompanying the fiscal year 1985 Labor-HHS bill that encourages you to make the balance of $8.9 million in rural development loan funds available to qualified applicants?

Answer. The Department's proposed budget has requested that these funds be transferred to the Family Social Services account in the Office of Human Development Services to assist in offsetting prior year claims and current year costs in the foster care and adoption assistance programs. In line with the administration's efforts to reduce the deficit, transfer of these unobligated funds would be helpful, while not imposing any hardship on existing RDLF recipients. This program presently has approximately 35 million dollars in outstanding loans which would be unaffected by the proposed transfer.

Question. Are you telling us bill language is again needed to force you to comply?

Answer. The Department's proposal for use of the RDLF is presently before the Congress. The Department will implement whatever decision results from the legislative process concerning use of this program funding.

Question. Since you received 110 applications in 1983 and were only able to fund 12 loans, is there any question about finding highly qualified applicants?

Answer. The Department's proposal to transfer the unobligated balance of the RDLF as of September 30, 1984 ($12,064,658) to the Family Social Services account in the Office of Human Development Services is not based on being unable to find qualified applicants. This proposal is part of the administration's attempt to reduce the budget deficit and is, I think, particularly appropriate because, as of March 1985, the existing RDLF intermediaries had approximately $11.5 million available for subloans without any additional funding from OCS.

COMMUNITY ACTION AGENCIES

Question. Can you tell us how many community action agencies have ceased to exist in the past four years?

Answer. We are unable to determine how many community action agencies have closed in the past four years because States are not required to report such data to OCS.

COMMUNITY FOOD AND NUTRITION PROGRAM

Question. Why do you oppose funding the Community Food and Nutrition Program?

Answer. The Administration has not requested an appropriation for the Community Food and Nutrition Program (CFNP) for Fiscal Year

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1986 because the CFNP is a part of the CSBG Act, as amended, which the Administration is seeking to have repealed.

In this period of increased employment opportunities and high deficits, another federally-funded food assistance program is not warranted. In Fiscal Year 1984, the cost of the present array of such programs---the food stamp, WIC, child care, school lunch, school breakfast and commodity distribtution programs---will have exceeded $19 billion. When compared with 1980, this represents a 36% increase in nominal expenditures and a 15% increase in real expenditures, (i.e., expenditures deflated by the 1980 and 1983 Consumer Price Indices for food at home).

For Fiscal Year 1986, the Administration is requesting additional increases in most food distribution programs, or a total increase of $250 million in food expenditures.

The $20 billion array of food assistance programs will be applied in Fiscal Year 1986 directly to the problems of hunger and malnutrition among the poor. The CFNP, on the other hand, if funded, would be used to encourage the proliferation of advocacy activities benefitting mostly the staffs of special interest organizations.

Question. I understand one of the purposes of this program is to provide small grants in the range of $50,000 for organizations to help make the poor aware of their eligibility for Food Stamps, School Lunch and Breakfast programs, Child Nutrition, and so on. Isn't it true that these feeding programs are underutilized by the needy individuals they were intended to serve? What efforts are currently being made to advise eligible persons about existing food programs?

Answer. The nutrition programs are administered by the Department of Agriculture (USDA). HHS does not maintain data on rates of participation by eligible populations for these programs. With respect to efforts to advise persons of their eligibility, some CSBG funds are used by CAAs to conduct informational activities relating to these programs. We believe that this use of CSBG funds largely duplicates the informational activities carried out by USDA.

Question. Do you realistically expect community action agencies to survive if we agree with your proposal to eliminate their block grant funding, and force them to compete with expanding needs for such activities as day care and services to the elderly?

Answer. It is quite possible that some CAAs, particularly those which have not been effective in the past in mobilizing non-Federal support, may have to suspend operations. However, we believe that a majority of the CAAs will survive if the CSBG is terminated. As I have pointed out a number of times in my testitimony, the loss of Federal funding resulting from the elimination of the CSBG will be relatively slight---only 12% of all CAAs' budgets. I believe that by pooling the administrative cost allowances authorized under other Federal programs delivered by CAAs (Head Start, LIHEAP, etc.), most CAAs will be able to offset the loss of CSBG funds.

In addition, there is no reason why CAAs which have been performing well should not be able to compete successfully for grants and contracts to deliver day care services, services to the elderly and other services. In fact, many county welfare offices are

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now using CAAs to deliver such SSBG-funded services as child care services, family planning services and home management information and referral servcies. The CSBG is not necessary to insure a CAA role in the delivery of these services.

CHILDREN'S TRUST FUNDS

Question. Given that the National Center on Child Abuse and Neglect held a special forum last June to highlight the importance of Child Abuse Prevention Trust funds, why did the Administration refuse to request any appropriation for the newly enacted legislation to provide Federal Challenge Grants for States establishing Children's Trust Funds?

Answer. The Children's Trust Funds are important and we would encourage all States to establish them to provide additional sources of funding for chiid abuse and neglect prevention and treatment activities; however, this should be a State decision. We now have the programs located in the National Center on Child Abuse and Neglect which provide funds to State and other agencies for child abuse and neglect programs and do not feel that creating another separate categorical program in this area is sound.

Question. If you feel that it is true that all States can establish such funds without any Federal incentive, how do you explain recent activities in Nebraska, Wyoming, Hawaii and Oregon to set up trust funds which have been prepared by this legislation?

Answer. We do believe that all States can establish Children's Trust funds without any Federal incentive. There are now 25 States which have such funds. We are glad to see that Nebraska, Wyoming, Hawaii and Oregon have begun the process of setting up funds. We do think that States must make their own decisions and that most, if not all States, will create Children's Trust Funds without Federal incentives.

Question. Given that this legislation meets basic Administration philosophy by encouraging States to set up their own special funds to pay for prevention activities, how do you explain your lack of support?

Answer. We are most supportive of State efforts to set up Children's Trust Funds and to date 25 States have done so with a number of others expressing interest or undertaking to do so. The special forum held under the auspices of the National Center on Child Abuse and Neglect is clear evidence of our interest and support of this concept.

USE OF SOCIAL SERVICES BLOCK GRANT FUNDS

Question. CSBG funds economic development programs, credit unions - one in New Haven, Connecticut, for instance - rural

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development, resource mobilization to name a few. What percentage of SSBG funds are spent on these programs?

Answer. Based on our review of 1984 pre-expenditure reports, no Social Services Block Grant funds are spent on these kinds of activities.

CAA's ADMINISTRATIVE COSTS

Question:

Would you please provide the committee with data on the comparative administrative costs of equivalent Head Start, Low Income Energy Assistance, and Job Training Partnership Program under community action agencies and the other providers that deliver these services? My understanding has always been that CAAs had the lowest overhead rate of any of the service providers.

Answer:

We do not have data on the comparative administrative costs of equivalent Head Start, Low Income Home Energy Assistance, or Job Training Partnership program by types of providers that deliver these services.

Questions Submitted by Senator Ted Stevens

Question. $11 million in FY 85 funding is authorized for the Family Violence Prevention and Services Act (Title III of P.L. 98-457). Please advise the Committee of the minimum amount of time required by the Department for the start-up of this program, once an appropriation is enacted. Please indicate the minimum time needed for each component of the start-up (such as the promulgation of regulations) as well as the total.

Answer. The Administration believes that providing funds for the new Federal program to combat family violence would be duplicative of existing programs, costly, administratively complex and inconsistent with the objective of allowing States and localities maximum flexibility in addressing local problems. At this time, in the absence of an appropriation for this program, no specific analysis has been undertaken related to resources needed or time required to start up a family violence program.

Question. Please advise the Committee of what could be accomplished towards start-up of the family violence program within the following timeframes subsequent to the enactment of an appropriation: Five months prior to the end of FY 85, four months prior to the end of FY 85, three months prior to the end of FY 85 and two months prior to the end of FY 85. Please indicate the amount of funds which would be expended within the above timeframes following an appropriation.

Answer. The Department has already begun to implement the administrative and information provisions of the Family Violence

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Prevention and Services Act. The President's FY 86 Budget requests no funding for this program.

Question. Please advise the Committee of what action has been taken to date to implement the provisions of the Family Violence Prevention and Services Act, in particular those provisions--such as the government-wide coordination of family violence prevention and services activities, including research and training--which can be handled within exisiting departmental structures and resources?

Answer. The Department has undertaken efforts to implement administrative and information provisions of the Family Violence Prevention and Services Act.

Recently, the Secretary invited other Federal agencies to participate in an interagency meeting that will be held in late April which will be the initial step to coordinate Federal activities concerning the prevention and treatment of family violence. In addition, plans are underway to expand the family violence information and guidance collection in PROJECT SHARE, a Department operated human services clearinghouse. PROJECT SHARE provides assistance to local persons and groups who need information and "how-to" guidance for a wide range of issues. In an effort to assist local communities and service organizations, PROJECT SHARE is developing a family violence resource guide, which should be available within the next few months. There is also a clearinghouse the Department operates specifically for child abuse matters.

Question. In the report produced last fall by the Attorney General's Task Force on Family Violence, the following recommendation was made: The Federal Government should provide financial incentives and encouragement to the States to train criminal justice personnel, to conduct a family violence prevention and awareness campaign, and to maintain temporary resident facilities for victims of family violence.

The Family Violence Prevention and Services Act would provide incentives and encouragement to the States for the activities named by the Attorney General's Task Force. Please advise the Committee of the factors behind the Department's decision not to request funding--for an FY 85 supplemental or for FY 86--for the program, assuming that these factors are more than simply budgetary considerations.

Answer. In September 1983, the Attorney General announced the creation of a citizens task force on family violence charged with providing specific recommendations for action to address the problems of family violence. The task force's final report made numerous recommendations to the Attorney General for action at all levels of government, including a recommendation for Federal financial incentives for training, public awareness campaigns and temporary shelters for victims. However, the task force report did not necessarily imply that the only means of Federal support and encouragement would be a narrowly defined administratively complex categorical program.

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We believe a new Federal program to address family violence is duplicative of existing Federal activities. Furthermore, creation of an additional categorical program is inconsistent with the Administration's objectives of allowing States and communities maximum flexibility in addressing local problems. The most effective responses to the problems of family violence are those developed by local communities, not new, cumbersome and administratively complex categorical programs.

The Federal Government already provides various support programs which can assist local governments to combat the crime of family violence. Within the Department of Health Human Services alone, there are a number of programs addressing different aspects of family violence. For example, the Social Services Block Grant provides funds to States which may be used for a wide range of social services, including those that may address family violence. The Child Abuse and Neglect Prevention and Treatment program assists States, local and voluntary organizations in preventing, identifying and treating child abuse and neglect. The Department also administers health block grants which can fund services to prevent and treat the problems of family violence. In addition, the Department funds research projects examining the issue of family violence.

Questions Submitted by Senator Mark Andrews

ELIMINATION OF THE COMMUNITY SERVICES BLOCK GRANT

Question. The Administration is basing elimination of the Community Services Block Grant (CSBG) on the assumption that services provided under the program are currently duplicated under other programs, primarily the Social Services Block Grant (SSBG). Could you explain your rationale?

Answer. The Administration's rationale for the elimination of the CSBG is based on the fact that the CSBG duplicates other Federal programs in two different ways: (1) a very substantial portion of CSBG funds is used to supplement administrative costs for delivering $2.4 billion worth of other Federal programs, each of which dispose of administrative allowances adequate to deliver these programs without the increment of CSBG funds and (2) the remainder of CSBG funds are used for direct services which are generically identical with those provided under the Social Services Block Grant.

It is the position of the Department that while there are some differences between the CSBG and SSBG block grants, these are minor and do not justify two entirely separate administering bureaucracies and sets of regulations at the federal level and, in many cases, at the State level.

The populations served by the two block grants, though not identical, largely overlap. Under both grants, services are provided to low-income people. With respect to the services delivered, we are not suggesting that the specific services provided under the two block grants are identical, although in some cases these do overlap (as in the case of child day care services). We are claiming, rather, that the various services provided under the CSBG and the SSBG are identical in kind: they are all "social services" or "human services".

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There are no substantive difference in the mechanisms used by the CSBG and the SSBG to deliver their respective packages of social services. The SSBG is operated mainly through county welfare offices while the CSBG is operated mainly through community action agencies. But the differences are not so pronounced as to justify two separate block grants. SSBG funds can be used by county welfare offices to subcontract for services from community action agencies. In fact, many county welfare offices are now using community action agencies to deliver such SSBG-funded services as child care services, family planning services, and home management information and referral services.

Differences in intent and purpose between the SSBG and CSBG are more apparent than real. As noted in the opening statement, historically the community action agencies were supposed to "focus resources on the goal of enabling low-income people to become fully self-sufficient". But two of the five goals of the SSBG also relate to the achievement of self-sufficiency by poor people. The CSBG Act speaks of ameliorating the causes of poverty while the SSBG Act seeks to prevent dependency. Dependency is a consequence of poverty. To combat one is to combat the other. To make explicit the link between poverty and dependency and to insure that States will have the authority to use SSBG funds for CSBG-type activities, the Department has proposed amending the SSBG Act to add "alleviate poverty" to the purposes section of the Act.

The problem of costly duplication of social services delivery systems at the State and local level was noted by the Institute for Local Self-Government (ILSG) in its report on the CSBG in June 1982. The Institute commented: "The human services system in most States is a patchwork of categorical programs, block grant programs and combinations of the two. The way the system has developed over seventeen years has created problems of several programs providing the same services, clients that must receive basic services from as many as five or more different programs and certain needy populations that receive no service at all."

The movement to consolidate social services delivery systems is well underway at the State level. For example, a January 1982 report on the SSBG by the American Public Welfare Association notes that "Kentucky and Massachusetts are looking at ways to eliminate duplication of services provided under Title XX (now the Social Services Block Grant) and under the Community Services Block Grant". (Parenthesis added). We believe that in the interest of economy, efficiency and greater flexibility for the States, Congress should pursue the idea in the first sentence of the SSBG Act and merge the two block grants. The first sentence of the Act reads, in part: "For the purposes of consolidating Federal assistance to states for social services into a single grant...".

Question. It is my understanding that aside from the issue of services provided, the difference between the SSBG and the CSBG relates to the fact that the former is geared towards direct assistance. Therefore, we are talking about a short-term solution. CSBG, however, goes beyond the aspect of direct assistance by providing the types of services which encourage individuals to help themselves. It seems to me that getting people off the welfare rolls and onto the road to self-sufficiency should be our ultimate goal. Yet by elimin-

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ating these services, aren't we implicitly perpetuating reliance upon federal assistance?

Answer. Two points need to be made in answer to this question: (1) the differences in intent and purpose between the SSBG and CSBG are more apparent than real since both block grants are supposed to encourage self-sufficiency, yet both are largely engaged in providing a range of social services to offset the effects of poverty and (2) there is no evidence that the anti-poverty activities conducted over the years by OEO, CSA and currently by OCS have had any significant impact on breaking the cycle of poverty. In reality, the network of 860 community actions which receives the bulk of the CSBG appropriation has become essentially a social services delivery system alongside other such systems---such as the SSBG network.

The fundamental similarity between the statutory purposes of the CSBG and the SSBG is evident from a comparison of the language in each statute. Section 675 of the CSBG Act states that CSBG funds will be used "to provide a range of services and activities having a measurable and potentially major impact on causes of poverty". This is consistent with the historical goal of community action agencies which was, in the words of the Economic Opportunity Act, "to enable low-income families and individuals to become fully self-sufficient". But two of the five goals of SSBG Act also relate to the achievement of self-sufficiency by poor people. The CSBG Act speaks elsewhere of "ameliorating the causes of poverty", while the SSBG Act speaks of preventing dependency. But dependency is a consequence of poverty. To combat one is to combat the other.

Question. Another assumption with respect to eliminating the CSBG is that the states will be able to fund a number of the program's activities themselves. In North Dakota, there are seven community action agencies, not including the Williston branch office. I have been informed that without federal funding, six of these seven offices will be closed down. Undoubtedly, other states will be in the same position. What is your response?

Answer. It is quite possible that some CAAs, particularly those which have not been effective in the past in mobilizing non-Federal support, may have to suspend operations. However, we believe that a majority of the CAAs will survive if the CSBG is terminated. North Dakota, for example, estimates that most of its CAAs would continue to operate their major programs from administrative and programmatic funds furnished from other federal authorities. As we have pointed out on a number of occasions, roughly 85% of the funding support for CAAs derives from Federal funding authorities other than the CSBG, such as the Head Start Program, the Low Income Home Energy Assistance Program, etc. Only 12% of CAA funds are supplied by the CSBG. In addition, much of this 12% is used for administrative overhead incident to the delivery of the other Federal programs mentioned above. This means that a relatively small portion of the total range of activities conducted by CAAs will be affected by termination of the CSBG.

Possible sources of funding support for such activities, where they are deemed by the States to be of high priority, include: (1) the Social Services Block Grant; (2) savings which the elimination of the CSBG can be expected to produce through consolidation and streamlining of social service delivery systems at the State level; (3)

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surpluses in State treasuries (projected to be $5.3 billion in FY 1985); and (4) private sector resources.

Questions Submitted by Senator Arlen Specter

FUNDING OF ANTI-POVERTY PROGRAMS

Question. The Administration is attempting to eliminate the Community Services Block Grant (CSBG) program again this year. In my state, these dollars are the core funding for 33 community action agencies which serve some 1,845,877 poor individuals.

If the CSBG funds are eliminated, 32 of the 33 community action agencies would have to reduce services by 75 to 90 percent, which will result in a loss of services to the poor, and will cost 2,500 to 3,000 low income employees of the agencies to lose their jobs.

Community action agencies in Pennsylvania provide services which include child care, housing assistance, weatherization, information and referral services, transportation, and emergency energy assistance.

The Administration contends that clients served under the CSBG program can be picked up under the Social Services Block Grant (SSBG) program, however no additional funds have been requested. In addition, the SSBG only serves 218,000 persons in Pennsylvania.

How do you propose that states fund anti-poverty programs out of Social Services Block Grant dollars without an increase in the budget for the Social Services Block Grant Program?

Answer. Of the six categories of services mentioned in the question, four are supported from Federal funding authorities other than the CSBG. Child care is supported by the Social Services Block Grant, housing assistance by HUD programs including the Community Development Block Grant, weatherization by the Department of Energy's Weatherization Program, and energy assistance by the Low Income Home Energy Assistance Program. Each of these funding authorities makes available to deliverers of their services (in many cases community action agencies) sufficient administrative funds to operate the programs. Elimination of the CSBG should not affect the delivery of services under these programs.

With respect to the relatively few activities supported exclusively from CSBG funds, possible funding sources which could replace the CSBG include: (1) the Social Services Block Grant; (2) savings which the elimination of the CSBG can be expected to produce through consolidation and streamlining of social service delivery systems at the State level; (3) surpluses in State treasuries (projected to be $5.3 billion in FY 1986); and (4) private sector resources.

As noted many times in my testimony, the CSBG represents only 12% of the total CAA budget. 86% of the funding support for CAAs derives from Federal funding authorities other than the CSBG. Contrary to the theory which views the CSBG component of CAA funding as the "glue" which holds all the rest together, it is clear to me that

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these other Federal programs would continue to be delivered without the CSBG. And there is no reason why CAAs which have been performing well should not be able to compete successfully for grants and contracts awarded to carry out these programs.

It is quite possible, of course, that some CAAs, particularly those which have not been as effective as others in mobilizing forms of support other than Federal funding, may have to suspend operations. However, I believe that a majority of the CAAs will survive if the CSBG is terminated. I must emphasize that while I would feel sympathy for employees of some CAAs who might lose their jobs as the result of termination of the CSBG, the purpose of the CSBG is not to provide a source of income for CAA staff but to relieve the plight of poor people served by the CAAs. The impact of termination of the CSBG on CAA staff is hardly a reason to continue, in a period of budget stress, expenditures which are duplicative.

Question. The Senate Special Committee on Aging estimates that in 1983 26 million persons were assisted through programs administered by 861 community action agencies around the country. Do you have reports or statistics which indicate that this population no longer needs services?

Answer. We have no reports or statistics that low-income persons no longer need services. The bulk of services to low inocme persons are provided by programs which collectively form the "social safety net" and for which the Administration is requesting $68 billion in FY 1986.

FOOD AND SHELTER FOR THE HOMELESS

Question. Does your task force have evidence that there is not a need for Federal assistance in providing food and shelter for the homeless?

Answer. There are substantial existing resources that can be applied to the problems of the homeless. It is the view of this Administration, a view which I firmly support, that instead of creating new programs of Federal assistance, a concerted effort should be made to target more of the existing resources on the homeless.

Resources currently available and expected to be available in FY 1986 include: (1) the federal entitlement programs; (2) federal block grants; (3) surplus federal foodstuffs, buildings and equipment; (4) state and local budgets; and (5) cash or in-kind support available from the private sector.

Many of the homeless are eligible for entitlement benefits such as food stamps, Medicare, Medicaid, Aid to Families with Dependent Children (AFDC), Supplemental Security Income (SSI), Social Security Disability Insurance (SSDI) and various veterans benefits. In addition to the entitlement programs, there are a number of other programs including block grants to the states that state and local governments can use, at least in part, to serve the homeless. These include the Community Development Block Grant, the Preventive Health
and Health Services Block Grant, the Alcohol, Drug Abuse and Mental Health Services Block Grant, the Social Services Block Grant, the

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Primary Care Block Grant, the DOE Weatherization program, and ADAMHA research.

With regard to surplus federal resources, in the case of food, under this Administration, between 1980 and 1984, the value of commodities distributed to needy families, schools, charitable institutions, and the elderly more than doubled---from $1.1 billion in 1980 to $2.5 billion in 1984. In addition, $50 million was appropriated in fiscal years 1984 and 1985 to support distribution costs incurred by the State distribution offices.

In addition, an agreement between DOD and HHS provides for military commissaries, with the approval of their suppliers, to donate their nonmarketable foodstuffs to food banks around the country that in turn donate the food to institutions feeding the needy. To date, there are 123 food banks joined with 224 commissaries. We are working hard to improve linkages.

The goal of focusing more surplus food and other surplus Federal resources on the problems of the homeless can be achieved only through cooperation (1) among the federal agencies which control these resources; (2) between these agencies and units of state and local government and (3) between governmental agencies at all levels and the private sector. To facilitate such cooperation, the Federal Task Force for Food and Shelter for the Homeless was created in November 1983 by Secretary Heckler.

The Task Force has negotiated ten agreements with federal agencies to support local food and shelter operations. These include agreements with (1) HUD & USDA (FmHA) for single-family homes in their inventory to be used as shelters, (2) DOD for the renovation and lease of DOD facilities for use as shelters, and for the donation of non-marketable commissary foodstuffs to foodbanks, and (3) GSA for the lease of vacant federal buildings to be used as shelters and for the donation of surplus federal supplies and equipment to foodbank and shelter operators.

The efforts of the Task Force have resulted, among other things, in federal buildings in Seattle, California, Denver and Washington, D.C., being made available for use as shelters.

State and local governments constitute another source of assistance to the homeless. In fact, most State and local governments are in much better fiscal condition than the Federal government, and thus better able to absorb the cost of feeding and sheltering the homeless. Forty-eight of the 50 states projected surpluses for FY 1984, for a total surplus of $6.3 billion. Local governments recorded surpluses for every year in the 1980-1983 period: $2.2 billion in 1980; $5.4 billion in 1981; $6.2 billion in 1982; and $4.1 billion in 1983. The Treasury Department has estimated that the combined state/ local surplus will total $65 billion by 1990.

Finally, a very considerable potential for helping the homeless exists in the private sector. The vast majority of the efforts to assist the homeless, are in fact, being undertaken by the private sector, including businesses, local non-profit groups, churches and synagogues, other voluntary organizations and individual volunteers. For example, 54 percent of shelters are operated by non-religious private groups, 40 percent by religious groups, and 6 percent by city

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and county governments. A variety of private sources provided 63 percent (or $138 million) of the 1983 operating expenses for all shelters. In addition, an average of four volunteer staff hours per bed per night was donated to shelters.

The private sector has also been actively involved in building new multi-purpose shelters such as those being built for the homeless almost entirely with private dollars in San Diego, Denver and Washington, D. C.

The Reverend Joseph Carroll in San Diego, for example, has raised almost $3 million in private funds toward a five million dollar shelter for the homeless. Construction began on March 23, 1985. Construction will also begin this summer on another model shelter in Denver, Colorado. The archdiocese of Denver has purchased a plot of land for $2.4 million and has raised $3 million from private sources of an estimated $4 million needed to cover building costs. In Washington, D. C., Jubilee Housing Inc., purchases and renovates local dilapidated buildings to meet the housing needs of the poor. Renovation is now underway on a $1 million emergency shelter supported solely through the voluntary efforts and financial contributions of church and community members. An exciting new dimension was added to the work of Jubilee when the Enterprise Foundation of Columbia, Maryland selected Jubilee Housing as the primary demonstration program for its national low-income housing support effort. The privately-funded Foundation issues grants for low-income housing projects, including projects for the homeless, in nearly two dozen cities across the country.

Question. What assurance do you have that states and local governments will be able to provide the necessary services without Federal support?

Answer. Homelessness is essentially a local problem. The problem originates at the community level and the focus of efforts to resolve it must be at this same level. The needs of the homeless are best assessed at the local level and it is only there that the appropriate support and assistance can be pulled together and delivered creatively and with caring. More and more cities and counties are beginning to realize this and are taking the lead by organizing partnerships between and among businesses, churches, private individuals, care providers and state and local service agencies to establish shelter and rehabilitation facilities for the homeless.

Many states and localities are already spending significant amounts on the homeless. According to the May 1984 HUD Report to the Secretary on the Homeless and Emergency Shelters, about 80 percent of local governments (cities and counties) do at least one of the following: operate shelters; give money to private groups to operate shelters or other services; lease or rehabilitate buildings for private shelter providers; and furnish vouchers to homeless persons for use in hotels, motels and apartments.

In the past, States have provided services mostly by "passing through" to local governments monies from federal sources such as the Federal Emergency Management Agency, HHS (through the Community Services and Social Services Block Grants), and HUD (through the Com-

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munity Development Block Grant). Recently, a few States (Maryland, New Jersey, California, Massachusetts and New York) appropriated substantial sums to provide either social services or shelter for the homeless. For example, New York has committed $21 million for construction during FY 1985. In addition, a commission appointed by Governor Cuomo has just recommended allocating $330 million in additional state funds over the next five to eight years for community-based services for the mentally ill. The commission also urged establishment of a system of financing to assure that mental health funds "follow the patient" from the institutions, with each local agency being held accountable for care in its area.

With improvement in States' fiscal condition, more and more States can be expected to follow the example of New York.

ABOLISHING ANTI-POVERTY PROGRAMS

Question. Once again your budget proposes to abolish the Community Services Block Grant, and consolidate its activities under the Social Services Block Grant---a net cut of $368 million in anti-poverty services.

Why do you persist in submitting this request, when the response of Congress has been to maintain and expand funding for the nationwide network of community action agencies?

Answer. We continue to submit the request for the elimination of the CSBG for the reasons given in my opening statement: (1) part of the CSBG is used for administrative costs related to other Federal programs for the poor and this duplicates the administrative overhead already authorized for these programs; (2) part of the CSBG is used for direct services not offered through the other Federal programs administered by the CAAs and this duplicates the SSBG, in terms of statutory purpose, the types of services offered and the clientele served; and (3) part of the CSBG is used for discretionary programs which duplicate identical programs funded by other Federal agencies. In this era of huge Federal deficits, we believe this kind of duplication is not acceptable.

The question implies that the elimination of the CSBG is tantamount to the elimination of the CAA network. We deny that this is the case. The CSBG represents only 12% all CAAs' budgets. We believe that a majority of the CAAs would be able to use the remaining 88% of their income to continue to serve poor people.

Question. Didn't the Congress extend the Community Services Block Grant legislation just last fall, raising the authorization to $415 million?

Answer. The Congress, in the Human Services Reauthorization Act of 1984, amended the Community Services Block Grant Act to raise the authorization in FY 1985 to $400 million and in FY 1986 to $415 million, but did not extend the CSBG beyond FY 1986---the year through which it was authorized in the original legislation.

Question. What services do you expect would be reduced with another $400 million cut?

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Answer. Although we are requesting the full authorization of $2.7 billion for the SSBG in FY 1986, we realize this may not be sufficient to fund all of the activities which were funded separately in FY 1985 under the CSBG and SSBG. States will have the option of continuing to fund CSBG activities which have demonstrated effectiveness. Those CSBG services which are not funded will be, we believe, ones which States feel have lower priority or have not proven their effectiveness. In these times of fiscal constraint, States can be expected to drop low priority SSBG activities in order to fund former CSBG activities which they believe have greater utility. Since the relative urgency of social services needs varies from State to State, it is not possible at the Federal level to generalize on the types of services States may choose to reduce.

RUNAWAY YOUTH PROJECTS

Question. Will HHS seek to award grants to additional shelters in FY 86 while maintaining level funding?

Answer. While the overall budget remains the same, the proportion of that budget which is devoted to funding shelters will rise from $18.16 million in Fiscal Year 1985 to $18.5 million in Fiscal Year 1986. This will enable the Department to fund five more shelters without necessarily affecting the funding available to existing shelters.

Question. How can the existing shelters continue to operate on level funding in light of increased operating costs and more youth necessitating assistance?

Answer. One of the most encouraging developments in the implementation of the Runaway and Homeless Youth Act has been the success of many centers in finding other non-Federal sources for financial support. This has enabled them to compensate for increased operating costs.

Questions Submitted by Senator William Proxmire

AVERAGE GRADE ESTIMATE

Question. On page 25 of last year's justifications you estimated an average grade of 10.50 in 1985. Your current estimate is 12.68. Why were you so wide of the mark?

Answer. The increase in the estimated average grade is primarily due to the relatively high loss of lower grade employees. As the time the Office of Human Development Services operates under a total freeze lengthens, the loss of clerical personnel compared to the loss of higher graded professionals increases. In a depressed hiring market it is easier for clerical personnel to move among agencies. Professionals tend to remain where they are during periods of hiring freezes.

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SPECIAL STUDIES AND ANALYSES

Question. Last year at this time you were estimating an expenditure of $40,000 for special studies and analyses in 1985. Your current estimate is $1,886,000. What caused your initial estimate to be so wide of the mark?

Answer. At the time the initial 1985 estimate for special studies and analyses was developed, without any information from our policy and development office, the estimate for 1984 ($42,000) was straight lined into 1985, with a small reduction. However, since that time, plans have been developed to fund special studies and analyses at a level of $1,886,000.

FOSTER CARE

Question. Secretary Hardy, on August 30 you received a memorandum from the Inspector General summarizing the results of 36 audits of the Foster Care programs administered by 28 States. The final audit reports recommended recoveries of over $69.3 million with 85 percent of the questioned costs appearing in the New York and California programs.

The Inspector General specifically indicated that substantial cost savings might be achieved if program officials provided more technical assistance and guidance to those two States. What steps are you taking to implement this recommendation?

Answer. The Inspector General found that the States, especially New York and California, were claiming various unallowable costs. We have issued clarifying action transmittals and memoranda on those costs, have disallowed the unallowable and will be training regional office staff on unallowable and allowable costs so that they can assist States in limiting their claims to allowable costs.

CHILD ABUSE

Question. Secretary Hardy, late last year the Justice Department issued a study that found people arrested for crimes against children generally receive shorter prison sentences than if they committed similar offense against adult victims. It seems to me the outcome should be just the opposite since children are so much more vulnerable.

Is your office making any effort whatsoever to see that children are given better protection by the criminal justice system?

Answer. The Department of Health and Human Services is deeply concerned about the handling of children in the criminal justice system. The National Center on Child Abuse and Neglect (NCCAN) is currently funding a project with the American Bar Association's National Legal Resource Center for Child Advocacy and Protection designed to help jurisdictions improve the prosecution of child abuse cases and reduce the emotional suffering of the children because of the court

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process. In addition the supplemental funding announcement of the NCCAN for Fiscal Year 1985 is soliciting grant applications in project areas which relate directly to this issue, including trauma to children inflicted by the legal system and training for judges and other professionals involved in handling child sexual abuse cases.

HDS - Committee Directives

Question. Secretary Hardy, last year the Committee included four directives affecting your shop in its report on the Labor-HHS-Education Appropriation bill.

The Committee asked you to prepare a report on the extent to which respite care services are currently available to families and on the agency's plans for meeting future requirements. Apparently that report, which was due prior to our hearing, has not yet been submitted.

The Committee report also included directives to maintain funding for certain specified aging research and demonstration programs, to increase funding for other specified research and demonstration programs, and to provide funding for National Legal Service projects.

In each instance your justifications indicate you are considering the Committee's directive. Why haven't you been more responsive to the Committee's directive?

Answer. The Office of Human Development Services assures the Committee of its concern about the importance of these issues and will take into consideration every indication given by the Committee in the implementation of these laws. However, with respect to the discretionary awards process, we believe that Federal stewardship is best served by the competitive grant review process. The value and type of awards finally made will depend on the relative merit of each application and the total number and quality of applications submitted in each priority area.

Question. I should warn you that if we are unable to gain your cooperation in carrying out directives contained in report language, we may be forced to place those directives in the bill itself. Do you realize that this is a distinct possibility?

Answer. With respect to a discretionary awards process, we prefer a competitive approach in which the value and type of awards depends on the relative merit of each application. We do not believe that virtually guaranteeing funding to certain organizations or interests best serves the people whom the programs are intended to benefit.

FINANCIAL ASSISTANCE GRANTS

Question. Last year you estimated that you would make 165 financial assistance grants to Native American organizations in 1985. Although you received a modest increase in your budget request, you will end up providing 219 grants in 1985 and the size of the average grant to Federally recognized Native

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American organizations will be about $1,100 less than your initial estimate.

Can you tell us why your initial 1985 estimates were so wide of the mark?

Answer. The Administration for Native Americans (ANA) is a discretionary program. Grants are awarded to the best qualified applications on a competitive basis. The Administration for Native Americans does not establish any upper or lower limits on the size of the grants it will fund, basing its decisions on the competitive merits of the application. Therefore, it is difficult to predict the exact number and size of the grants to be funded.

REQUEST FOR NON-PERMANENT POSITIONS

Question. I note that your current estimate for the full-time equivalent of non-permanent positions in fiscal year 1985 is 201, that is a substantial increase over last year's estimate of 122 in fiscal year 1985. Can you tell us why you have decided to hire two-thirds more temporaries in 1985 than you estimated you would last year?

Answer. The 201 includes 56 full-time equivalents for Stay-in-School employees that do not count against ceiling, but who do contribute to the total compensable work years. In the past, these have not been reported, but in the 1986 Justifications they are included for the first time.

HDS CONSULTING SERVICES

Question. The cost of HDS consulting services will apparently be about twice as high as your initial estimates in 1984 and 1985. Last year's justifications indicated you would spend $1,025,000 on consultants in 1984 and $1,008,000 in 1985. You actually spent $2,098,000 in 1984 and your current estimate is way up to $2,441,000. Can you tell us why you have had to spend so much more than you originally projected in this area?

Answer. In fiscal year 1984 the Office of Human Development Services spent additional funds in this area for external reviewers for Head Start expansion and Runaway Youth applications received in response to Federal Register announcements for the availability of Federal financial assistance.

SUPPORT FOR PROJECT CONTRACTS

Question. Last year you estimated you would be spending $14,040,000 in project contracts in 1985. Your current estimate is $8,453,000. Can you tell us where you took the cut?

Answer. Project contract estimates for 1985 were reduced to comply with Public Law 98-369, the Deficit Reduction Act of 1984.

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Question Submitted by Senator Daniel K. Inouye

FUNDING CYCLE

Question. The funding cycle for Native American programs, which provide social and economic self-sufficiency for American Indians, Alaskan Natives, and Native Hawaiians, is not scheduled to start until December 1985. What provisions are being made to provide for interim costs incurred prior to this new start date?

Answer. ANA makes funds available to grantees as soon as these funds are released to us. We typically have open competitions for funds in Oct., Feb., and June, permitting applicants to compete several times thoughout the year. There is no need to provide for interim costs prior to a new start date because ANA provides funds for specific projects which will be successfully completed during the funding period.

Statement of Senator Mark Andrews

THE CSBG IS A PROGRAM THAT ADDRESSES A NUMBER OF CRITICAL NEEDS, NEEDS THAT AS A COMPASSIONATE SOCIETY WE SIMPLY CANNOT IN GOOD CONSCIENCE IGNORE. IN ORDER TO DEMONSTRATE THE RELEVANCE OF THIS PROGRAM, I RESPECTFULLY SUBMIT EIGHT CASE HISTORIES FROM MY OWN STATE, WHICH I BELIEVE ILLUSTRATE ITS EFFECTIVENESS AND IMPORTANCE AS A MEANS OF ADDRESSING POVERTY IN THE UNITED STATES.

CASE HISTORY #1

Community Action started working with this family of five in November of 1982. When they first came to our office, they were in need of housing and food stamps. Because of the husband's ill health and back surgeries, he was unable to provide for his family. He also had a language barrier because of his Hispanic origin, which made it difficult for him to understand the English language. Because of this barrier, he was unable to communicate with employers even though he was capable of the work responsibilities. We helped this family obtain Public Housing and Food Stamps. We then started concentrating on getting them assistance through Social Security. We referred them to Legal Assistance for assistance with his Social Security claim. Legal Assistance indicated that they didn't feel that he had a legitimate claim. We chose to pursue the Social Security claim, and in November of 1984, after two hearings, we were notified that his claim had been approved for benefits. He received his first lump sum check of $4,668.00 on March 8, 1985, which he immediately deposited in a Savings Account in a local bank. On March 11, 1985, we began negotiating with a lending institution for them to purchase their own mobile home. They will now be home-owners instead of renters and the husband is now employed at a job which pays him $5.00 per hour, 40 hours per week. He will now be able to support his family. We continue to counsel this family on their Budget.

CASE HISTORY #2

Community Action started working with this couple in June of 1981. When they first came to our office, they were in default on their Mobile Home Loan. We did a Budget work-up on them. After going through their budget, we contacted their lender and were able to establish a new payment plan for them, which lowered their payments. While working with them, we discovered that the husband should be eligible for Social Security benefits. Upon persuing this, we were able to get him on Social Security benefits in April of 1984. With continued Budget Counseling and the additional income into the household, they are now current on their Mobile Home Loan and their utilities. They are now responsible for taking care of their own insurances. They have established good paying habits and have learned where their priorities should be.

CASE HISTORY #3

Community Action started working with this family of four on July 31, 1982. They were referred to us for HUD Counseling by their lending institution because they were four months in default on a VA Home Loan. We filed for a HUD mortgage assignment. They were granted the assignment in November of 1982, which set them up with a new payment plan for a three year period. They have been able to abide by this new pay-

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ment plan faithfully. The reason for the default on their Home Loan was because the husband had been on 100% VA Disability for fifteen years and in 1982, his disability was changed to 80%. This caused a large decrease in their monthly income. During this period of assignment, the family has had a chance to reorganize their finances. They come in each month to make their payment to HUD through our Counseling Office.

CASE HISTORY #4

Community Action started working with this family of four on June 7, 1983. They were referred to us by their lending institution because they were in default on their Home Loan. After doing a budget sheet on them, we filed for a HUD mortgage assignment in which we were denied. After receiving the denial, we talked to their lending institution and made arrangements for an extention on their contract and approval to make a payment and a half until the default was brought current. In September of 1984, the default was cleared up and they are now making regular scheduled payments on their home. Her husband is now working full-time and she is working part-time. The reason for the default was due to economic conditions in our area. He was a Commercial Painter and because of the low rate of construction, he was without work.

CASE HISTORY #5

Community Action started working with this family of two on January 3, 1985. This woman came to our office because of her financial situation. She had been cut in her hours at work and was behind in all of her bills. The first thing that we did was to go through her budget and figure out a pay-back plan. She was living on a very limited income and had many bills to pay. After going over her budget, we made calls and wrote letters to her creditors to negotiate a payment plan that we could all agree on. She was two and a half months delinquent on her rent payment, and we were able to get a donation for her to pay half of the amount due. We negotiated with her bank on her car loan and were able to get her loan extended and cut down to half the amount that she was paying to free up some money to pay her other over-due bills. She had her income tax done at our agency by VITA and will be receiving an income tax refund which will bring the balance of her over-due accounts up-to-date.

CASE HISTORY #6

Community Action started working with this family of six on October 13, 1983. The mother came to our office for assistance because they had no heat, food, or income. The reason for this was that the father of this family had been sent to the State Penitentiary. We contacted Pierce County Social Services and went over this familie's case history. Pierce County Social Services was able to give this family Medical Assistance for the children, AFDC, and Food Stamps. We called the Department of Energy in Bismarck and got a waiver under the Fuel Assistance Program to go out and inspect the heating system. Upon inspection, it was determined that the system in place was unsafe and they would not approve fixing it. Under the Emergency Energy Program, this family was granted the money for the installation of a new heating system. Because of this, she and her children now have a safe and warm home.

CASE HISTORY #7

Community Action started working with this women on August 10, 1983. She had just been through a Drug and Alcohol Rehabilitation Program. She was displaced, had lost her husband and her home. She was looking for a new beginning. We assisted her in finding low-income living quarters for which she had no money to pay for. We paid the first months rent from a donation that we received from a Fraternal Organization. She obtained employment in the first week. On her third week, we took her to a lending institution that agreed to give her a personal loan to live on until she received her first paycheck. I was notified by the bank that she had met her obligation faithfully and that they were very impressed and pleased that they had taken a chance. She now lives in a nice apartment and is working full-time. She seems to have her life in order now. She keeps in contact with us to let us know how she is doing.

CASE HISTORY #8

On December, 1984, it was reported to Community Action, by a Board Member, that an elderly couple in their seventies were in need of assistance. This couple lives in a one room house in a rural area. Their house has no running water, electricity, or heating system. This couple sleep on rags on the floor of their house. They have no transportation, except an old tractor. Assistance has been offered, but because of personal pride, any effort to help has been rejected. We are now in the process of trying to figure out a way to reach these people.

This is just a small example of the rigid pride many North Dakotans seem to have when it comes to accepting assistance.

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SUBCOMMITTEE RECESS

Senator WEICKER. The subcommittee will be in recess until Tuesday, April 16 at 9:30 a.m. when we will hear testimony from the Secretary of Education as well as from representatives of the following Department of Education offices: Departmental management, salaries and expenses; Office for Civil Rights; and the inspector general. Thank you very much.

[Whereupon, at 10:25 a.m., Thursday, March 28, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, April 16.]

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DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1986

TUESDAY, APRIL 30, 1985

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 11 a.m., in room SD-116, Dirksen Senate Office Building, Hon. Lowell P. Weicker, Jr. (chairman) presiding.

Present: Senator Weicker.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

DEPARTMENTAL MANAGEMENT

STATEMENT OF JOHN J. O'SHAUGHNESSY, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET

ACCOMPANIED BY:

THOMAS McFEE, ASSISTANT SECRETARY FOR PERSONNEL ADMINISTRATION

ROBERT B. HELMS, PH.D., ACTING ASSISTANT SECRETARY FOR PLANNING AND EVALUATION

JOHN HOPKINS, DIRECTOR, DIVISION OF OFFICE OF THE SECRETARY BUDGET SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

PREPARED STATEMENT

Senator WEICKER. To present the fiscal year 1986 budget request for general departmental management of HHS is John O'Shaughnessy, Assistant Secretary for Management and Budget.

Why don't you introduce those who accompany you, and then we will get right down the road. Your statement in its entirety will be placed in the record, and you may proceed in any way you want.

[The statement follows:]

STATEMENT OF JOHN J. O'SHAUGHNESSY

I am very pleased to be here to present and justify the fiscal year 1986 budget request for the general departmental management [GDM] appropriation. For fiscal year 1986, the budget proposes $135.7 million in obligational authority, including $8 million

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in transfers from the Social Security trust funds, and 2,412 full-time equivalent [FTE] staff.

Although the $135.7 million GDM budget represents only a very small portion of the Department's total $330 billion request for fiscal year 1986, the resources included in the GDM budget play a very important role in fulfilling the Secretary's responsibilities to formulate policies, implement programs, and manage the resources of the entire Department. The GDM appropriation supports those activities that are associated with the Secretary's role as a policy officer and general departmental manager, as well as those that provide direct and specialized staff support services performed on a centralized basis in the Office of the Secretary [OS] for the operating divisions of the Department. These activities include: policy analysis, legislative liaison, budget formulation, personnel management, financial management, legal services, payroll and personnel data system services, and grants management and payment services.

The fiscal year 1986 request for $135.7 million and 2,412 FTE's includes savings of $3.9 million and 90 FTE's below the level proposed for fiscal year 1985. These savings result from a number of management actions aimed at reducing overhead and increasing efficiency throughout the Office of the Secretary [OS]. Included in the $3.9 million savings estimate are: reductions associated with the proposed 5-percent decrease in Federal employees' pay; reductions from the proposed 90 FTE savings; and reductions in the cost of renting and maintaining office space for employees of the Office of the Secretary which result from efforts to consolidate such office space.

Partially offsetting these fiscal year 1986 savings, the budget also proposes increased funds for management initiatives which we believe will yield additional budget savings in future years. We are recommending an additional $750,000 to further develop a uniform accounting and administrative information data system which, when fully operational, would eliminate overlap among duplicative systems in the Department's operating divisions. We are also proposing $772,000 to renovate switching facilities in order to install integrated voice and data communication equipment, which could save over $100 million in future years. Finally, the budget proposes a total of $3.8 million to renovate buildings occupied by OS employees in order to facilitate the consolidation and reduction of office space used, and to reduce the amount needed for rental of such space.

The fiscal year 1986 GDM budget request builds on the management improvements achieved through the Office of the Secretary streamlining process presented to the subcommittee in the fiscal year 1985 budget justification, and completed in August 1984. Under the OS streamlining initiative, the Department reduced the size of the Office of the Secretary by several hundred work-years over a relatively short period of time, without an adverse effect on the quality of essential work performed and without the involuntary separation of a single employee. In fiscal year 1986, we will continue to streamline operations in the Office of the Secretary by better targeting our resources and increasing productivity.

Mr. Chairman, by continuing to prudently manage hiring and employment throughout the Office of the Secretary, by taking advantage of efficiencies available through new computer technology, and by improving the way we organize and manage our work, the $135.7 million GDM budget request for fiscal year 1986 will allow the Secretary to sustain a strong record of leadership and excellence in managing the programs and agencies of the Department.

INTRODUCTION OF ASSOCIATES

Mr. O'SHAUGHNESSY. Thank you, Mr. Chairman. I have on my left, Mr. Tom McFee, the Assistant Secretary for Personnel Administration. To his left is Dr. Robert Helms, the Acting Assistant Secretary for Planning and Evaluation. Then on my right is Mr. John Hopkins, Director, Division of Office of the Secretary Budget Services.

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OPENING STATEMENT

We are very pleased to be here to justify the 1986 budget request for general departmental management. For fiscal year 1986, the budget proposes $135.7 million in obligational authority, including $8 million in transfers from the Social Security trust funds, and 2,412 full-time equivalent staff positions.

Although the $135.7 million budget represents only a very small portion of the Department's total $330 billion request for 1986, the resources included in the budget play a very important role in fulfilling the Secretary's responsibilities to formulate policy, implement programs, and manage the resources of the entire Department.

The general departmental management appropriation supports those activities that are associated with the Secretary's role as a policy officer and general departmental manager, as well as those that provide direct and specialized staff support services performed on a centralized basis in the Office of the Secretary for the operating divisions of the Department.

These activities include: policy analysis, legislative liaison, budget formulation, personnel management, financial management, legal services, payroll and personnel data system services, and grants management and payment services.

Mr. Chairman, I will submit the rest of my statement for the record.

RESTRUCTURING REGIONAL OFFICES

Senator WEICKER. The 1986 budget proposes a restructuring of the general departmental management accounts. I note that the regional offices now are under your Office's direct control. Is this a first step toward closing these regional offices?

Mr. O'SHAUGHNESSY. At this time, Mr. Chairman, we are proposing to study efficient and effective delivery of services in our regional offices. We have no plans to close regional offices. Before any such plans were made, we would come to the Congress and notify the Congress as to what our plans would be. That study is only just beginning.

Senator WEICKER. How do you plan to respond to the OMB directive for Cabinet-level departments to reduce to three regions?

Mr. O'SHAUGHNESSY. At one point in the negotiations with the Office of Management and Budget that was a preliminary directive. The final directive given was that every agency should study efficient operation, and that is what we are now doing.

MOBILE TELEPHONES

Senator WEICKER. How many administrative personnel in HHS have mobile telephones in their automobiles?

Mr. O'SHAUGHNESSY. Twenty-five.

Senator WEICKER. How much is this costing the Department each month?

Mr. O'SHAUGHNESSY. It is $3,000 or $3,200, in that range.

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Senator WEICKER. Why is this necessary?

Mr. O'SHAUGHNESSY. Given the demanding nature of the work schedules of the individuals involved, it seemed to be an efficient way to do business, particularly as a number of our officials have to travel quite a bit between Baltimore and Washington.

Senator WEICKER. I don't have one in my car.

Mr. O'SHAUGHNESSY. I don't either, and frankly I would pay to keep it out.

Senator WEICKER. You are saying that it is $3,500 roughly for those mobile phones.

Mr. O'SHAUGHNESSY. It is a little bit less than that, but in that range.

Senator WEICKER. How many are there altogether?

Mr. O'SHAUGHNESSY. Twenty-five.

Senator WEICKER. This is $3,500 total for the 25 phones?

Mr. O'SHAUGHNESSY. Yes; it is $3,200, I think.

Senator WEICKER. It is $3,200.

PLANS TO RENOVATE OFFICES

You are asking for $3.3 million to renovate offices for employees and the Office of the Secretary. What will be accomplished by expenditure of the $3.3 million and why is this renovation being done during a period of fiscal restraint? What will be renovated in the Office of the Secretary, and how much money applies to that?

Mr. O'SHAUGHNESSY. We are trying to reduce office space by about 350,000 square feet over the next few years, and we want to renovate approximately 250,000 square feet in the next year at a cost of about $15 a square foot. The idea is to consolidate the staff which is spread through several buildings in the southwest Washington area.

Senator WEICKER. Dr. Helms is here, so why don't you proceed on the policy research appropriation. There are other questions for response to the record.

PREPARED STATEMENT

Mr. HELMS. I have just a few remarks, and I will submit the testimony for the record.

I am pleased to be here to request an appropriation of $6 million in fiscal year 1986 for policy research. This year we have reviewed the objectives of policy research very carefully and have carefully targetted funds into the most policy-relevant research. In addition, fiscal year 1985 funds are being used to conclude two multiyear projects, like the health insurance experiment for which 1986 is the last year, and the monthly reporting project.

We think that policy research is an essential part of the Department's work. We have put emphasis on research that is cross-cutting in nature and, therefore, will not be performed by the operating divisions.

We will be happy to respond to any questions.

[The statement follows:]

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STATEMENT OF ROBERT B. HELMS

I am pleased to be here today to present the FY 1986 budget request for the Policy Research appropriation administered by the Office of the Assistant Secretary for Planning and Evaluation. The requested funding level of $6 million will support research in the areas of health, income security and employment, and human services policy. This research provides information for the Congress, the Department, other Federal agencies, States and others about human resource policies and programs, and about the anticipated effects of policy changes.

Goals and Strategy of the Policy Research Programs As you are well aware, the Department of Health and Human Services is responsible for planning, operating and evaluating many programs to help meet the Nation's basic health, social service and welfare needs. The Policy Research program is designed to improve our understanding of issues affecting HHS programs and the problems they are meant to alleviate, and to enhance our ability to develop effective policies. It examines policy issues that cut across organizational and subject lines, and has a much broader focus than research conducted by HHS's Operating Divisions.

The crosscutting nature and flexibility of this program allows us to examine important issues, such as improvements in the delivery and financing of long-term care, problems of high-risk population groups, the relationship between public and private sector retirement plans, and reforms in the financing and delivery of health care.

We have shifted the focus of the Policy Research program from large-scale multi-year experiments to short-term studies. This focus will provide more timely information and allow us to respond more quickly to the needs of both the Executive and Legislative branches. It also has enabled us to reduce the Policy Research budget, which was $24 million in FY 1980.

Health Policy Research Health Policy research is directed primarily toward the analyses of incentives to encourage cost-effective changes in health care financing and service delivery. There are two principal categories of research. Health Incentives research will continue to provide information on how best to enhance competition in the health care delivery system. During FY 1986, several studies will address private sector innovations in controlling health expenditures. We will complete a study of worksite preventive health projects, assessing the cost effectiveness of different types of company-sponsored health enhancement programs. We also will complete a study of preferred provider organizations which many employers are using to contain employee health care costs.

Research will continue on geographic variations in health care expenditures, identifying the underlying reasons for the differences, their impact on quality of health care, and any changes in expenditure patterns that might stem from implementation of prospective payment for hospitals under Medicare.

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These studies are designed to provide us information to understand the dynamic change that is underway in the nation's health care system. Results from the research should enhance our understanding of the effect prospective payment is having on the financing and delivery of health services. We are hopeful that the research results will also furnish important insights into ways Medicare may move beyond prospective payment into a competitive method of purchasing health care for the aged and disabled.

Analysis of the results of the Health Insurance Experiment (HIE) will be completed in FY 1986. The experiment, which started in 1972, has developed a wealth of information on the effects different consumer cost-sharing arrangements have on health care utilization and status.

It has already influenced the public and private policy debate. The most well known finding is that cost sharing reduces medical spending significantly, a result still debated and not conclusively settled in the 1970s. By randomly assigning participants to health maintenance organizations, the experiment also demonstrated that HMOs practice a different style of health care treatment than the fee-for-service sector, and that HMOs can create real savings which are not due to selection of low-risk enrollees.

In recent years, all estimates of the impact of cost sharing on utilization have used parameters developed or critically evaluated based on information provided by the HIE. The cost-sharing results have also been used in private sector negotiations to increase deductibles in employer-based group health insurance policies. The HMO findings have been cited by advocates of the use of alternative delivery systems.

Much of the major analytic work in FY 1986 will address the impact of different types of insurance plans and cost sharing arrangements on quality of care and health status. In addition to publications, data from the experiment will be made available to the public in the form of public use tapes which are in final stages of preparation. These files will provide a data-base rich in detail on utilization, expenditures, health status, and quality of care. They will be a major source of data for research on policy analysis for years to come, informing both the public and private sectors on the impacts of possible reforms.

Income Security and Employment Policy There are two major groups of studies on income security and employment policy planned for FY 1986. The first, Welfare Policy Studies, will seek further ways to promote the transition of welfare recipients to self-sufficiency through private sector employment and increased child support payments, thereby reducing dependence on public sector programs. Research will continue on absent parents and their ability to pay child support, and examine implementation of requirements for medical support by such parents. The latter study--which addresses the interface among child support, private health insurance, and Medicaid--will assist in implementing the 1984 amendments to the Child Support Enforcement program and in preparing the Congressionally-mandated report on this problem area. Both studies will help identify ways to improve child support.

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Research also will investigate labor markets accessible to those on welfare, and how best to structure work programs to help welfare recipients find employment. Clearer understanding of these markets and ways to improve access to them are important when considering how to promote employment as a route off welfare.

Retirement Policy Studies will address issues concerning retirement income and savings across the entire spectrum of public and private retirement programs. In particular, research will address the interaction between social security and private savings and pensions, focusing on enhancing the role of private savings, insurance, and pensions in providing income for the elderly. Research will also address the aggregate effects of public and private retirement income programs on the economy, and continue work on the effects of increased use of employers' fringe benefit programs and tax-deferred retirement savings accounts on social security.

In addition, research will continue on poverty-related issues. The FY 1985 Policy Research appropriation includes $1.75 million designated by the Congress for research conducted by the Institute for Research on Poverty at the University of Wisconsin. This funding will support research by the Institute in both FY 1985 and 1986.

Human Services Policy--Long Term Care studies will continue to identify trends in the administration, financing and delivery of long-term care, and provide information concerning strategies designed to increase the role of the family and the private sector in the provision of long-term care, in order to help prevent and reduce dependency among the elderly and disabled. In FY 1986, research will focus on completion of a model that will be used to examine the supply and demand for long-term care services under different policy options. Research also will examine the effect of types of housing, and the availability of services, on the need for long-term care and probability of institutionalization.

Research on Competition and Private Sector Initiatives will continue to identify ways to improve the efficiency of the delivery of social services, and on employer, family and community provision of social services in order to help reduce dependency. In particular, projects will examine private sector social services--such as employer sponsored day care--to identify the effectiveness and efficiency of such services, and barriers to their expansion. One study will examine the role of employer-financed services, and the impact of potential tax policy changes on them.

Conclusion I believe that the Policy Research program, even at reduced levels of funding, can continue to contribute significantly to informing decision-makers on some of the most difficult social policy issues facing our nation. At an extremely modest investment, it provides a ready means for targeted research on pressing policy concerns.

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ACCESS TO HEALTH CARE

Senator WEICKER. Recent reports indicate that 35 million Americans do not have reasonable access to health care because of inability to pay. I understand you have just completed a study on uncompensated care. How big is the problem of uncompensated care, and does your study verify the 35 million figure?

Mr. HELMS. The study is actually not being done by my Office under policy research, but by the Health Care Financing Administration. I don't think that it is really finished yet. I could let HCFA respond to that.

Within the planning and evaluation area we are concerned with uncompensated care and regard it as a very important issue for future policy development. We are considering funding one project on uncompensated care, and doing a considerable amount of work internally. Therefore, our present efforts do not appear in the policy research budget.

I will add that it is very hard to define uncompensated care. I noticed that in yesterday's paper, the Census Bureau published the 35 million figure, too, and we think that that is about right. I think that there are a lot of interesting questions that can be asked about that population, for example, the extent to which they have coverage from other kinds of sources.

Senator WEICKER. The 35 million figure, as I understand it, are those that have no coverage at all, period.

Not from the private sector, not from anywhere.

Mr. HELMS. I believe the 35 million figure refers to people who do not have adequate insurance. Such people may include those who have health insurance part of the year. Of course, many of these people obtain free care from hospitals and from community health centers and other kinds of public and private facilities.

DECREASE IN WELFARE POLICY RESEARCH

Senator WEICKER. I note that the largest decrease in your fiscal year 1986 budget request is for welfare policy research, a decrease of 40 percent. What research projects will be impacted by this decrease?

Mr. HELMS. Three factors contribute to the decrease. First, we will be funding smaller projects, and many of the larger projects previously funded were in the welfare policy area. Second, the Institute for Research on Poverty was funded on a 2-year basis covering fiscal year 1985 through fiscal year 1986. While there is nothing in the budget request for them in 1986, the Institute will utilize almost $900,000 that year, principally projects in the welfare policy area..

In addition, several welfare policy projects, such as the multiregional policy impact simulation model [MRPIS] will be completed in 1985.

Although we are cutting down somewhat, we are trying to get the Institute for Research on Poverty to redirect some of their research into the areas that we think are of high priority, particularly the homeless, and some projects concerning Indians, Hispanics, and the disabled.

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QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator WEICKER. I have further questions for response to the record, both to Mr. O'Shaughnessy and Mr. Helms.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

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Questions Submitted by the Subcommittee

GENERAL DEPARTMENTAL MANAGEMENT

Regional Offices

Question. Your FY 1986 budget proposes a restructuring of the General Departmental Management accounts. I note that the Regional Offices now are under your office's direct control. Is this the first step toward closing these regional offices?

Answer. The Administration's general policy is to reduce the number of Federal regions to "the minimum number consistent with cost-effective program delivery."

Our FY 1986 budget request does not assume any specific plan for consolidating regional offices.

Question. How do you plan to respond to OMB directive for cabinet-level departments to reduce to three regions?

Answer. Just recently OMB asked us to examine the question of field office structure for HHS agencies. We are now starting to look at the size and number of different field offices we need to deliver program services effectively and efficiently.

If after studying this issue, we conclude that offices should be consolidated, without interrupting or decreasing essential services, we will:

- o inform the Congress of any plans to consolidate before we implement them;
- o attempt to consolidate or reduce without any major reductions-in-force; and
- o seek to carry out these reductions within the overall budget levels now proposed in our FY 1986 request.

Mobile Telephones

Question. How many administrative personnel in DHHS have mobile phones in their automobiles?

Answer. The Department has 25 mobile telephones for use by 38 officials.

Question. How much is this costing the Department each month?

Answer. The monthly cost to the Department is between $3,000 to $3,200.

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Question. Can you justify this expenditure?

Answer. The demanding nature of the work schedules kept by the officials of the Department is such that the time spent in automotive travel (a significant amount of which is between Washington and Baltimore) can be now put to better use with the aid of mobile telephones. Decreased cost and increased availability of mobile telephones no longer allow cost considerations to be a prohibition to their use.

Question. How do you determine who gets the phones?

Answer. The phones are installed in the Department's motor vehicles most frequently used by senior officials. Also, one phone is installed in a messenger vehicle allowing the messenger to be rerouted while on pick-up and delivery schedule.

86 FTE Loss vs. Regional Offices

Question. You are proposing yet another reduction in FY 1986 of 90 FTEs. How many of these FTEs will be taken from the Regional offices?

Answer. Approximately 50 FTEs will be saved by attrition in Regional Offices in FY 1986.

Question. Will any RIFs be required in the regional offices if consolidation of the regions occurs?

Answer. The FY 1986 budget does not presume any consolidation of regional offices. All FTE savings are the result of attrition.

Question. If offices are closed and RIFs are avoided -- does that mean employees will be transferred?

Answer. At this point, we are studying the entire matter of regional office needs. I would not want to prejudge the outcome of that review. However, if major changes are proposed that would result in closing regional offices and transferring large numbers of employees to different regions, we would certainly advise the Committee before we proceed.

Question. What happens to a young employee who may be living at home and earning $18,000 and is transferred?

Answer. We have no plans to close any regional offices. However, if consolidations do take place, the Committee can be

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assured that the Department would make every effort to find employment in the same geographic area for such employees.

Office Renovation

Question. You are asking for a $3.3 million to renovate offices for employees and the Office of the Secretary. What will be accomplished by expenditure of the $3.3 million and why is this renovation being done during a period of fiscal restraint?

Answer. This is part of the effort to decrease office space for Federal employees to an average of 135 square feet per person.

We plan to renovate up to 250,000 square feet of office space for OS Staff Divisions covered by the GDM appropriation. Average renovation costs are about $15 a square foot.

This renovation will include changing walls, moving telephones, pulling all communication cables (including computers) as well as the actual cost of moving furniture, and equipment.

By doing this, we expect to reduce our office space requirements by about 350,000 square feet over the next two years.

At about $16 per square foot in rental costs for office space, we expect to recoup the $3.8 million investment over the next two to three years.

Therefore, this is a particularly good investment at a time of fiscal austerity.

FTE's FY 1985 Reprogramming

Question. On March 15th I received a reprogramming request that essentially proposed a spending plan different from last year's request. For example, a year ago your own office, Mr. O'Shaughnessy requested 889 FTE and $43.6 million. Now you are asking to reduce the FTEs by an additional 86 and $5.2 million. Why was this decision made?

How are you accomplishing your work -- I note your justifications were late once again?

Answer. We are accomplishing our work now and I do believe we will continue to do so at the staffing levels proposed for FY 1985 and FY 1986. At reduced staff levels we are finding that employees are indeed accepting new more challenging responsibilities. I think we are seeing more productivity of the staff we have. We have carefully introduced the use of personal computers in those offices that can benefit from them, and we are finding that workloads are being accomplished with fewer people. We are relying more on interoffice task forces and work groups to develop plans, initiatives and

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proposals, where appropriate, rather than relying on the development of lengthy issue papers and time-consuming comments among OS Staff Divisions. The work group approach deals with problems up front and avoids labor-intensive alternatives such as writing issue papers, rebuttals, and holding meetings to resolve minor areas of dispute.

For the "Management and Budget" activity the single largest decrease is $3.4 million which was initially budgeted for separation costs assuming several employees might have to be involuntarily separated under the OS Streamlining effort. Because no employees were separated, those funds were not needed.

About $2.7 million will be saved through hiring policies which are expected to gradually reduce employment throughout Management and Budget offices and in other OS Staff Divisions. By closely managing employment and new hires, we feel we can carry out the work of the Office of the Secretary, and reduce employment levels without any reductions-in-force.

About $.5 million will be saved pursuant to the reductions called for by Section 2901 of the Deficit Reduction Act of 1984, and Section 515 of the FY 1985 Treasury-Postal Services Appropriation.

Offsetting these reductions are FY 1985 increases associated with the 3.5 percent January 1, 1985 pay raise related salary costs.

Administrative Cost Reduction

Question. I note that your total request for FY 1986 is for $135.7 million, which is only about 3% less than the FY 1985 budget. I understand that the President's budget calls for a 10% reduction in administrative costs. Does your FY 1986 budget request meet this requirement?

Answer. We intend to fully achieve the 10 percent reduction in FY 1986. A ten percent cut from the FY 1985 appropriation for General Departmental Management would equal $14 million. Our FY 1986 budget does include $14 million in reductions from:

- o reducing staffing by 90 FTE ($3 million);
- o reducing employee's pay by 5 percent ($3 million); and
- o absorbing the effect of inflationary and employee pay increases as well as saving SLUC costs through space consolidation ($8 million).

New Financial Management System

Question. What is the "Financial and Administrative Integrated Management System"?

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Answer. FAIMS is a uniform data management system which we propose to use across the entire Department. This system will standardize different financial and management definitions and terms now used through separate, duplicative management systems of the Operating Divisions. FAIMS will integrate data management for:

- o Finance and accounting systems, including general ledger, accounts payable, funds control, debt management and accounts receivable;
- o Procurement, including purchasing, contracting, receiving and requisitioning; and
- o Logistics, including stock inventory and fixed assets (equipment and buildings).

In addition to eliminating overlapping and redundant data management systems in the Department, FAIMS will provide financial, procurement and logistics data faster, with greater accuracy, and at far less cost than now provided under the separate systems maintained by the Operating Divisions.

The key to FAIMS is the use of a common and integrated data base (common definitions of terms) designed to reduce multiple entry of common data and eliminate redundancies of separate OPDIV systems. In other words, FAIMS defines management terms more precisely and controls the quality of the data better by recording all relevant information -- accounting, procurement, equipment -- at a single point of entry, rather than allowing several officials to record the same information at different points in the procurement process.

FAIMS will be implemented through the use of propriety software packages. These software packages, which include a data base management system and integrated modules for different applications, will be used at three sites as part of a fully integrated system. The three sites are at the computer centers of NIH, PHS, and SSA.

In implementing the FAIMS system, we plan to install prototypes in two sites: at the PHS Computer Center for the Debt Management component and at the NIH Computer Center for other data elements.

Policy leadership for FAIMS is being provided through a policy working group which will oversee the design, development, and installation of FAIMS. Policy group members include experts in the different functional areas covered by FAIMS:

- o Finance/Accounting ... Deputy Assistant Secretary for Finance;
- o Procurement/Logistics ... Deputy Assistant Secretary for Procurement and Logistics;
- o Data Processing ... Deputy Assistant Secretary for Management Systems; and
- o the Inspector General as well as the Project Manager.

At each of the three Computer Center installation sites, a

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site manager has been appointed to manage installation of the system. That manager will assemble a team of functional experts and data processing technicians to facilitate installation. This use of in-house staff expertise is not only cost-efficient, but directly involves in the planning and design stage the agency officials who will ultimately use the FAIMS system. In this regard, the development of FAIMS is truly a Department-wide effort.

We expect testing and implementation of FAIMS will be completed in mid FY 1987, and the system will be operational by the end of FY 1987.

Cost of FAIMS

Question. You have requested $1 million in FY 1985 and you are requesting $1.75 million in FY 1986. How much will the system finally cost and how much will it save over the long term?

Answer. We estimate it will cost about $7 million to develop the system, plus the cost of 7 existing staff for planning, designing and implementation of this amount:

- o $3.3 million will be used to purchase software;
- o $1.9 million will be used to purchase terminals and for prototype testing (about 600 terminals); and
- o $2.0 million will be used for equipment maintenance and for employee training under the new system.

Once it is fully operational (end of FY 1987), the FAIMS system is expected to reduce annual operating costs by about $30 million. These savings result from eliminating duplicative manual workloads which will be accomplished through automation.

- o an estimated 1,250 fewer FTEs would be needed Department-wide, chiefly in accounting specialities;
- o these savings would be phased in beginning with the FY 1987 budget;
- o every effort would be made to achieve these staffing reductions through attrition -- we do not anticipate the need for any involuntary separations.

In addition to these long-term savings, we have already reduced costs in the short term by about $11 million through a moratorium on all other Departmental systems development in this area. The Operating Divisions had initially planned to spend about $19 million in systems improvements for 8 systems at 8 different locations over the 1984 to 1986 period. The $7 million we will spend to develop FAIMS, plus another $1 million in staff costs, produces $11 million in short term cost avoidance savings over this 3-year period.

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Child Abuse Awareness

Question. You indicate in your budget justification that you plan to coordinate efforts to increase public awareness to child abuse. Please describe how you plan to increase public awareness of this problem. How much will this effort cost and what are the expected results?

Answer. The Secretary's goal is to heighten awareness of the scope of the problem of child abuse and neglect.

The Secretary has personally examined the Head Start program and its existing hiring practices. The Department is developing a series of proposals designed to encourage grantees to tighten up hiring procedures now in place.

As you know, P.L. 98-457 charges this Department with coordinating the Federal response to family violence, a key component of which is child abuse. The Secretary has already contacted other Cabinet officials and agency heads advising them of the HHS role, and the first inter-Departmental meeting will be held this Spring. Federal agencies with programs relating to family violence prevention and assistance to victims will attend and exchange information.

Finally, the Secretary uses a variety of forums -- the print media, speeches to women's organizations and forums, and the electronic media -- to get the word out.

Costs associated with this effort cannot be estimated because responsibilities and activities are divided among several persons.

Public and Private Sector Participation

Question. What benefits will accrue by encouraging public and private sector participation in the Department's major initiatives?

How do you plan to accomplish this and how much will it cost?

Answer. We believe the public will benefit from its participation in the Department's major initiatives. The public and private sector groups will be a part of the process and will therefore have a greater interest in its success. Additionally, new concepts and ideas in the form of suggestions regarding content and approach to the target audience will be encouraged.

The additional resources provided by Public and Private Sector participation will result in wider dissemination of messages and information to the desired audiences.

The participation of private sector organizations in major Departmental initiatives will be accomplished through high level contacts between officials of HHS and those of private sector organi-

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zations. The goal is to establish a firm working relationship which will provide a base for continuing partnership and participation in major departmental initiatives. For example, ideas and concepts will be developed with government resources; and then be implemented by the private sector with nongovernment funds and resources.

Identification of contacts will be accomplished through the use of on-line data bases and consultants. The initial start-up and continuing work will cost much less than if the entire burden was on the Federal government.

The costs to the Immediate Office of the Secretary for this effort which includes personnel, on line data bases and necessary ADP equipment is $214,000. It should be noted, however, that these costs would be far greater should we have to implement these initiatives without private sector participation.

New Telecommunication System

Question. I understand that your present telecommunications system is furnished by GSA. Is that correct? Why, then, are you purchasing new telecommunications equipment during a time of fiscal austerity?

Answer. We believe that costs for the GSA-supplied CENTREX system will rise substantially over the next ten years -- from an estimated $15 million for HHS agencies in the Washington, D.C. area in FY 1987 to over $40 million in FY 1996.

An HHS telecommunications system could reduce these costs to less than $20 million in FY 1996, producing cost avoidance savings of $90 to $125 million over the ten year period.

Question. You are requesting $772,000 for purchase of this equipment in FY 1986. What are the out year costs?

Answer. The $772,000 is not to be used to purchase telecommunications equipment, but is necessary for renovation to prepare OS facilities for new communications equipment. While not final, our current plan subsequent to this renovation is for a "lease to purchase" arrangement for a telecommunication system, with costs over the 9 year period from FY 1988 to FY 1996 estimated at $146.7 million.

Estimated outyear costs for continuing under CENTREX over this 9 year period are $245.7 million. Thus we estimate the savings would be $99 million if the Department enters into a "lease to purchase" agreement with another system.

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Questions Submitted by Senator William Proxmire

Delinquent Student Loans

Question. Mr. O'Shaughnessy, last year we discussed the Department's efforts to collect an estimated $800,000 in defaulted student loans from appropximately 450 Departmental employees. Secretary Heckler indicated that the Office of Personnel Management was considering a new regulation which would allow the Department to offset this indebtedness against salary payments. Is this regulation in place and are you receiving payments from all of your employees who have defaulted on their student loans?

Answer. This Department received on January 16, 1985 a list from the Department of Education of 244 HHS employees who were delinquent in paying their debts under the Federally Insured Student Loan Program and the National Direct/Defense Student Loan Program. Of that list, 150 were identified as current HHS employees and 94 were returned to the Department of Education for further research.

Since that time 21 of the 150 employees were dropped from the list because the loans had been paid. Letters to the remaining 129 employees still delinquent were sent on March 9 informing them that salary offsets of 15 percent of their disposable income would begin after 30 days. The April 23 paycheck was the first affected. The total amount to be collected by the Department is $180,000.

The Department is authorized to perform this debt collection by Department of Education regulations approved by the Office of Personnel Management. The proposed regulations referred to in last year's testimony were submitted to OMB on November 2, 1984. The Department anticipates that these broader regulations which derive from the Debt Collection Act of 1982 will be published shortly.

Equipment Budget in FY 1985

Question. I notice that under the Departmental Management account you intend to spend $2,704,000 for equipment in fiscal year 1985 although your initial equipment estimate in last year's budget was $1,886,000. Can you tell us why you underestimated your 1985 equipment budget by over $800,000 last year?

Answer. The estimated equipment cost of FY 1985 was revised upward between the President's Budget Appendix and the Department's FY 1985 budget justification one month later. This was done because a more precise distribution among Other Services, Equipment and other cost categories was by then available for certain automated data processing systems still on the drawing board. The difficulty in estimating costs of such systems partially is due to the decisions made based on the relative advantages and disadvantages of owning vs. leasing ADP hardware and whether software must be purchased or created.

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Financial Integrity Act - FAIMS

Question. I understand that the Department is currently implementing a new Department-wide Financial and Administrative Integrated Management System (FAIMS). This system apparently will allow the Department to take corrective action in the areas of property accounting, receivables accounting and debt collection, and accounts payable accounting, areas that were highlighted in your 1983 Federal Managers Financial Integrity Act report. What is your timeframe for full implementation of the System at the Parklawn Complex and the Social Security Administration?

Answer. The Department plans to install FAIMS prototypes at two sites beginning this fiscal year: at the Public Health Service Computer Center at the Parklawn Complex for the Debt Management component of the system, and at the National Institutes of Health for other data elements. Testing and implementation of FAIMS will be completed by the middle of FY 1987 and the system will be operational by the end of that fiscal year.

Question. Has there been any slippage in the initial implementation milestone and, if so, why has this slippage occurred?

Answer. The project is progressing on schedule. It is presently at the developmental stage where Department-wide common and unique application requirements are defined and documented.

Question. I understand that although you began the implementation of such a system at NIH back in 1972, that implementation has not yet been fully completed. Isn't it likely that the application of the system to the entire Department will run into similar delays?

Answer. NIH as well as other agencies within the Department were developing financial and administrative systems during the 1970s in support of their respective management requirements. About the same time a system was also being developed for the Office of the Secretary. These 8 systems were being developed and maintained without common Department system and managerial objectives in mind. It was a very costly approach to system development, and led to major redundancies in systems design and maintenance. The systems had little or no capability to relate to each other. One of the greatest deficiencies was the lack of information and data available to the Department to exercise its oversight responsibilities. FAIMS is a Department-wide system utilizing a common data base management system and a single set of integrated application software to support the Department's financial and administrative functional needs.

A decision was made to design a single system for all users rather than the 8 separate and incompatible systems. There were no major delays in the NIH system. Further development was stopped in favor of the FAIMS single integrated systems. We do not anticipate

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major delays during the FAIMS implementation either, although it is a major development effort.

Question. Why has it taken so long to implement FAIMS at NIH?

Answer. FAIMS is the single integrated system of the entire Department and has been in the process of development for only 6 months. Department-wide functional requirements are defined and documented, a process that will be completed during the summer of 1985. This documentation will serve as the basis to modify a set of proprietary software products to be installed Department-wide; NIH will be one site, the Parklawn Computer Center and the Social Security Administration will be the other two.

During the period of functional documentation, the Data Base Management System (IDMS/R) will be installed and tested at each of the three sites. The Data Base Management System has been installed in the Parklawn Computer Center and will be installed in the Social Security Administration and NIH during the months of April and May of 1985.

Parts of the functional applications system (proprietary software packages modified to meet Department-wide needs) will be tested in prototype at each of the three computer sites. Currently, the General Ledger System is being tested at the Parklawn computer facility.

Question. What is the projected cost for the full implementation of FAIMS?

Answer. We estimate it will cost about $7 million to develop the system, plus the cost of 7 existing staff for planning, designing and implementation of this amount:

- o $3.3 million will be used to purchase software;
- o $1.9 million will be used to purchase terminals and for prototype testing (about 600 terminals); and
- o $2.0 million will be used for equipment maintenance and for employee training under the new system.

Once it is fully operational, at the end of FY 1987, the FAIMS system is expected to reduce annual operating costs by about $30 million. These savings result from eliminating duplicative manual workloads which will be accomplished through automation.

- o an estimated 1,250 fewer FTEs would be needed Department-wide, chiefly in accounting specialities;
- o these savings would be phased in beginning with the FY 1987 budget; and
- o every effort would be made to achieve these staffing

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reductions through attrition -- we do not anticipate the need for any involuntary separations.

In addition to these long-term savings, we have already reduced costs in the short term by about $11 million through a moratorium on all other Departmental systems development in this area. The Operating Divisions had initially planned to spend about $19 million in systems improvements for 8 systems at 8 different locations over the 1984 to 1986 period. The $7 million we will spend to develop FAIMS, plus another $1 million in staff costs, produces $11 million in short term cost avoidance savings over this 3-year period.

Question. Taking into consideration the implementation date of FAIMS, when does the Department expect to have corrected the weaknesses identified in its 1983 and 1984 Federal Managers Financial Integrity Act Reports relating to property, receivables accounting and debt collection, and accounts payable?

Answer. The property, receivables, and accounts payable functional areas are being developed as individual sub-systems within the total integrated systems, FAIMS. Although work has been done and will continue to be done to improve these functional areas during the FAIMS development, the current Department plans are to place into operation the total integrated system during FY 1987. The sub-system will be installed after being tested in prototype during late FY 1986 and FY 1987. Full deployment of FAIMS throughout the Department will follow a successful installation of the total integrated system in FY 1987.

REPROGRAMMING LANGUAGE

Question. Mr. O'Shaughnessy, last year for the first time the Committee included language in the Senate report on your appropriation bill directing that the Committee be notified prior to the reprogramming of funds in excess of 10 percent or $250,000, whichever is less, between programs, activities or elements.

Earlier this week I questioned the Director of the National Institute of Drug Abuse about a decision to cut funding for extramural research into cocaine and stimulants in fiscal year 1985 from the $5.9 million proposed last year to the $2.6 million shown in this year's budget request. Clearly this was a significant reprogramming. It is only one example of several that the staff has identified in your budget documents. Why haven't we been specifically notified of such reprogrammings in accordance with the language contained in last year's report?

Answer. Let me assure you that it is the Department's policy on the reprogramming of funds to obtain approval from the Chairmen of the House and Senate Appropriations Subcommittees prior to reallocating funds for different purposes.

We would make the distinction, however, between a reprogramming, which is a proposed reallocation of appropriated funds, and a change from a proposal included in the President's budget. The President's budget presents a theoretical spending plan assuming

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enactment of Administration proposals. The spending plan developed subsequent to an enacted appropriation bill may include adjustments for such factors as the directives provided in committee reports, floor colloquys, and conference action. Based on enacted appropriations, it is not unusual for differences to occur, especially at the subactivity level, from the President's budget to the final spending plan.

There is a distinction between amounts proposed for the budget year in the congressional justification and the spending plan adopted subsequent to the appropriation of funds. The spending plan amounts appear in the following year's justification as the current year column and represent the funding arrangement based on actual appropriations, directives,and other guidance provided by the appropriations committees subsequent to passage of the final appropriation bill. Thus, the differences you cite result from a spending plan which reflects the actual conditions under which we have to operate versus a proposed budget estimate which was presented many months in advance.

Questions Submitted by the Subcommittee

POLICY RESEARCH

UNCOMPENSATED CARE

Question: Recent reports indicate that 35 million Americans do not have reasonable access to health care because of an inability to pay. I understand that you have just completed a study on uncompensated care. How big is the problem of uncompensated care, and does your study verify the 35 million figure? Does the study suggest any leglislative solution to this problem? It is apparent that the cost of treatment for a medical condition increases as the condition grows more serious due to lack of care. Has your study addressed this problem?

Answer: The term "reasonable access" can have a variety of definitions. Several studies done over the past several years to try to identify the number of people facing financial barriers to adequate care had serious definitional problems and data limitations. Examples of these problems include calculations of the numbers of people who receive services through such direct delivery programs as the Indian Health Service and Community Health Centers, and those who are partly or wholly insured through State-only programs. As a consequence, research has tended to focus on persons who are uninsured all or part of the year in question. Recently, for example, the Urban Institute estimated that some 33 million persons under age 65 did not have insurance. Illustrative of the caution with which one must interpret such findings is the consideration that some of these persons have rather high incomes and choose to self-insure.

Beyond the number of uninsured, there are persons with insurance that is not comprehensive which might be defined by some as compromising "reasonable access" even though such levels of insurance may be a matter of personal economic choice.

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Section 603 of Public Law 98-21 requested that the Department conduct a study of uncompensated care. That report is being prepared under contract to the Health Care Financing Administration and is expected to be completed in June. That study is focused on the implications for the health care delivery system and for third-party insurers by virtue of the amount of health care that is provided each year without third party reimbursement, estimated at $6.2 billion in hospital charges in 1982. We do not have comparable figures for the amount of uncompensated care provided prior to the enactment of Medicare and Medicaid. Inasmuch as the study is not yet complete, it would be premature to attempt to either discuss or reach conclusions on the advantages and disadvantages of alternative solutions (including Federal legislation). There are a large number of questions about the population using uncompensated care, about the services provided, and about the costs of such care that could not be addressed in this rather short study which will need to be the subjects of additional research. The interaction of severity and timeliness of care is one such issue.

DECREASED FUNDING FOR FY 1986 WELFARE POLICY RESEARCH

Question: I note that the largest decrease in your FY 1986 budget request is for welfare policy research—a decrease of 40%. What research projects will be affected by this decrease?

Answer: We will continue to fund small-scale exploratory research in areas of direct policy relevance such as low-wage labor market studies and other areas of policy interest such as refugees and immigrants. We will also continue support for the Panel Study of Income Dynamics, a longitudinal study of economic well-being and income dynamics. Further, the development phase of the Survey of Absent Parents will be complete, and the operational phase will be supported by the Office of Child Support Enforcement.

The FY 1986 reduction is primarily due to the fact that our largest project, the Institute for Research on Poverty, was fully funded for two years using $1.75 million from the FY 1985 appropriation. Also, the Multiregional Policy Impact Simulation (MRPIS) model grant expires in December 1985.

The funds appropriated for the Institute in FY 1985 are sufficient to cover research on poverty through FY 1986, making it unnecessary to appropriate additional funds at this time. A two-year plan is most productive and less disruptive than endeavoring to accomplish this type of research in one year increments. The Institute will focus on the following areas in 1985-87:

- Economic status and program participation of Hispanics and American Indians
- The homeless
- Disability and long-term trends in health status
- Income
- Income transfers and welfare dynamics
- Relative economic status

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MRPIS is a large-scale, computer microsimulation model for use in the quantitative analysis of public tax, transfer, and expenditure programs. Funding for the model expires in December 1985.

CENTRAL AMERICAN REFUGEES

Question: Last year the Senate Report asked you to examine the impact of refugees and immigrants on the economy. Do you have any preliminary information that can be shared with the committee?

Answer: The FY 1984 appropriations bill requested that Department to study the effect of Central American refugees on programs developed under the Social Security Act (SSA). In response, we initiated research to explore the five year impact of these refugees on SSA administered assistance programs.

The first task--a review of statutes, regulations, and guidelines governing alien eligibility for Social Security Act and related programs--is complete. The most important finding is that the courts in recent years have broadened the definition of "permanently residing here under color of law," and hence have broadened the categories of aliens eligible for Federal welfare benefits. Depending on the outcome of cases still pending, even illegal aliens who will eventually be deported could be eligible for SSI or AFDC while their cases are being adjudicated.

BUDGET - POLICY RESEARCH

Question: Since 1976 policy research has received $192 million in appropriated funds. How has your research impacted upon the poor and disadvantaged in our society? Have results of this research justified the expenditure of $192 million?

Answer: The Policy Research program provides information for the Congress, the Department, other Federal agencies, States and others about human resource policy options. The crosscutting nature and flexibility of this program allows us to examine issues that affect HHS programs and the problems they are meant to alleviate. This includes, but is not limited to, problems of poverty and disadvantage.

Of the money spent since 1976, only 25% has been obligated by this Administration, and an even smaller percentage on new projects started since 1981. The contributions made by policy research over both the earlier and later years can be grouped into four categories: research responding to Congressional mandates, long-term (multiyear) research, small projects addressing short term policy issues, and research focused on upcoming policy issues. Each is described below.

1. Projects contributing to Congressionally mandated requirements. Recent examples include:

   - o Report on Approaches for Reimbursing Capital under Prospective Payment
   - o Report on Cafeteria Plans (Flexible Spending Accounts)

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- o Report on Central American Refugees
- o Research on Poverty (ongoing research at Wisconsin Poverty Institute)
- o Multiregional Policy Impact Simulation Model (ongoing research at Boston College)

Descriptions of each of these projects are provided in the Justifications of Appropriations Estimates for the Committee on Appropriations for FIscal Year 1986 already submitted to Congress.

2. Projects designed as long-term, multi-year research. Three large experiments have contributed substantially to public policy. These projects have accounted for more than three-fourths of total policy research expenditures since 1976.

- o The Health Insurance Experiment

This study was first funded in 1972. It was designed to measure the effects of alternative cost-sharing and other institutional arrangements on the demand for health care, the quality of care, and the health status of recipients. It has allowed us to simulate the effect of deductibles on health care expenditures and on the market for supplemental insurance. This information has already been used in many ways and will soon be used in a report to Congress on flexible spending accounts.

The experiment also provided much of the data used in developing the President's Health Incentive Reform package. The provisions for cost sharing under Medicare and the limit on the subsidy for employee-based health insurance were based on the findings.

More generally, the Health Insurance Experiment (HIE) has provided definitive evidence that savings achieved by HMOs represent genuine economies rather than enrollment by "good risks". As a result, lingering doubts about HMO performance have been laid to rest and both public and private sector initiatives to promote the use of HMOs have continued and expanded in the 1980's. Similarly, the HIE provided by far the best available evidence on the magnitude of savings achieved by coinsurance and deductibles in insurance plans, and has thereby encouraged reforms in the structure of both public and private sector plans in recent years.

- o Monthly Reporting Project

This project examines AFDC payment policies. It tests a requirement that AFDC families report income and changes in family circumstances on a monthly basis, with eligibility and the grant amounts based on information reported for the prior month.

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through this project a field test was initiated in Colorado. Because the results of this field tests were so promising, Congress, in 1978, directed the Assistant Secretary for Planning and Evaluation to undertake a special research effort to expand the depth and breadth of knowledge about monthly reporting policies.

Based on the initial findings from the Colorado demonstration, the Congress also required states to initiate monthly reporting for their AFDC caseload in the Omnibus Budget Reconciliation Act of 1981. Demonstration projects in Illinois (joint with the Food Stamp program there), Massachusetts, and Michigan were completed in 1982. Evaluation of these carefully designed research demonstrations is underway with reports on all the research being received monthly. The final reports on the research are due this summer.

- o Income Maintenance Experiment

  A substantial portion of Policy Research spending over the 1976-81 period was on the Seattle-Denver Income Maintenance Experiment. This experiment and its predecessors showed that:

  --Providing people with a guaranteed income significantly reduces the amount of labor force participation.

  --A high marginal tax rate had only a small effect on the amount of work done.

  --Participation in a negative income tax program significantly increases the likelihood of martial breakup.

3. Small scale projects designed to research specific short term policy issues. Significant ones include:

   - o Evaluation of Selected Hospital Capital Finance Issues has supported the Congressionally mandated study of Medicare Capital Funding and the PPS. The study illustrated how various industries address the problem of capital financing and provided lessons of use to hospitals.

   - o The data base on Employer-Sponsored Health Plans was used to assess various proposals to alter the tax treatment of employer-paid health benefits.

   - o Purchase of the Dunn & Bradstreet Data Files enabled us to analyze employee health care plans and to improve our estimates of the effects of a proposed limit on untaxed employer payments on employee health insurance. Our estimates of effect are being used in a report to Congress on Flexible Spending Accounts (Cafeteria Plans).

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- Our 1980-81 study of Head Start examined grantee cost accounting, enrollment, staffing, and service. The study resulted in a cost analysis system being introduced nationwide. As a result, Head Start has been able to increase enrollment with a relatively constant budget.

- Preliminary findings in our comparisons of public, non-profit and for-profit organizations suggest that services offered by for-profits may, in terms of quality, be equal to or better than those offered by other providers with comparable costs and client satisfaction. Thus, restrictions against for-profits appear unnecessary. As a result the Administration proposed and the Congress accepted modifications to the Runaway and Homeless Youth Act which permitted service delivery by for-profit firms. We plan to propose legislation this year to eliminate restrictions against for-profits in other HHS programs.

- Our research on retirement and aging examines determinants of economic behavior by the elderly. The papers produced cover a wide range of issues--pension coverage, disability, retirement behavior, the relationship between social security and labor supply, related economic status of the elderly and their living arrangements, savings behavior--and were recently published in Retirement and Economic Behavior by Aaron and Burtless of the Brookings Institution. These papers are the basis of the Department's study of the implications of raising the retirement age for Social Security.

- Another study has contributed to analyses of both earnings sharing in Social Security and taxation of Social Security benefits and on developing a microsimulation model of economic behavior. Findings were applied to analyses conducted for the 1983 Commission of Social Security and used in developing the details of the legislation to implement the agreed plan.

- Policy research funded a long-term evaluation of the court ordered deinstitutionalization of Pennhurst residents in the late 1970's. The study was the largest and most comprehensive study available and has shown that seriously handicapped institutionalized residents can be placed in the community. The result of this research continues to be examined by almost all States and have been instrumental in decisions to phase down institutions and develop community programs.

- In the late 1970's ASPE participated in an Interdepartmental Task Force on Worker's Compensation to which personnel and research funds were contributed. The efforts of the Task Force resulting in significant improvements in State worker's compensation programs.

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Seven research volumes, were produced and the findings have influenced States in areas such as benefit levels, data systems and payment promptness.

- o Residential care was comprehensively studied in the late 1970's. The study identified numerous problems among board and care homes, such as lack of adequate medical care and inadequate services. Findings have been widely disseminated and were extensively cited in the development of a Model State Statute for Board and Care Homes developed by the American Bar Association.

4. Projects that focus on upcoming policy issues, for example:

- o Our welfare dependency studies could lead to more efficient targeting of resources by focusing on long-term dependents, and our studies on low-wage labor markets will permit us to better focus job programs for welfare recipients. In addition, we have examined child support enforcement and medical support.

- o Our study of Private Sector Health Care Initiatives provides cost containment models that will be used to improve management of health care by the private sector, with potential impacts on a large fraction of the workforce.

- o Our study of Worksite Health Enhancement will be used to indicate where corporate resources are best spent in health promotion and how the public and private sectors can best combine their efforts to improve the health of workers.

- o Two projects are contributing to the Department's positions on refugee and immigration legislation: Assessment of Assistance Programs for Central American Refugees; and Research on Labor Market and Program Participation of Hispanics, Immigrants and Southeast Asian Refugees.

- o A 1981 Congressional mandate directed the Department to "encourage family involvement." We are conducting a research review and an assessment of several service programs to determine how to promote family involvement in the issues of teenage pregnancy, substance abuse and running away.

- o Several studies examine the implications of raising the Social Security retirement age. The results will be used in a mandated report to the Congress and will support preparation of several legislative proposals.

- o A major emphasis has been placed on projects to assess cross-cutting supply and demand determinants of long-term care. Demographic and longevity data indicate that there will be a rapid increase in the over-65 population over the next 35 years. The increase will

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be especially rapid in 1985-95, as those born in the 1920s become 65, and again in 2010-2030, as the post-World War II baby boom generation reaches that age. Although the major impact on federal programs such as Medicaid and Medicare on the private sector will not occur for about ten years, the impact will be severe.

— We have just completed a study on private sector financing of long-term care for the elderly. This project showed the practical and actuarial feasibility of numerous options such as adding long-term care insurance to life insurance policies and adding such insurance as a pension option. We expect that this study will have a substantial effect in stimulating private sector adoption of these and other alternatives, thereby lessening future dependence on Medicaid and other public programs.

-- Together, this and other long-term care studies planned for the next several years will provide a major source of information for the Department, the Congress, and the private sector in assessing present and future policy options.

JUSTIFICATION FOR FY 1986 DECREASE IN FUNDING

Question: Your budget requests have declined from $22 million in FY 1981 to $6 million in FY 1986. If your research has proven valuable and cost-effective, why are you decreasing your efforts? Why not close down the policy research operation?

Answer: Although our research has proven valuable and cost-effective, a reduction in funding for Policy Research is consistent with the Administration policy to hold discretionary spending as low as possible.

However, the reduction also reflects a shift in strategy for policy research, away from large scale multi-year experiments. We are continuing to phase-down these large projects--notably the Health Insurance Experiment and the Monthly Reporting project--as they are completed. These large demonstrations are being replaced by smaller, short-term projects designed to respond to more immediate needs for policy information. This allows us to reduce funding, and continue to perform useful policy research activities.

The Grace Commission recommended that we close down the policy research operation. This served as the catalyst for us to take a long and hard look at the relationship of Policy Research to the overall operations of the Department. After this careful examination, we concluded that for now policy research is useful for the Office of the Secretary, specifically to conduct cross-agency research on topics such as refugees, long-term care, retirement financing, and poverty. In keeping with the recommendations of the Commission, we have reduced the policy research budget from $15 million in FY 1983 to $6 million in FY 1986, targeting the funding to those studies that do cut across operating divisions, and focusing on relatively short-term and low-cost studies.

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Policy Research projects cannot be transferred to the operating divisions for the following reasons:

- All Policy Research projects are funded under this appropriation precisely because they do not belong in the operating divisions. It is the only flexible research authority available to the Secretary which may be used to examine issues of national policy significance.

- Projects undertaken in Policy Research are broader in scope than research performed by individual operating divisions or bureaus oriented to specific programmatic policies and procedures. HCFA research, for example, is oriented primarily toward important but program-specific problems such as alternative reimbursement policies for hospitals and other medical care providers.

- Furthermore, some of the research performed under this authority affects this entire Department and, occasionally, other agencies. For example, we address private sector activities and the interface with public programs. We have a joint project with HUD on housing for the elderly and its impact on long-term care.

One example which illustrates both our current research strategy and the value of retaining a modest program is the just-completed study, Private Financing of Long Term Care: Current Methods and Resources. This project addressed a wide range of alternatives for meeting the needs of the growing elderly population for all types of care, both in institutions and at home. It addressed private insurance with level premiums and indemnity benefits, prepaid care ancillary to HMO programs, life care centers, pension benefit options, combination life/long term care insurance and other options that extended far beyond current public programs such as Medicaid and aging programs. No other research programs of the Department had the mandate or expertise to cover such a broad range of options, extending far beyond current or potential Federal programs.

GEOGRAPHIC VARIATION IN HEALTH CARE COSTS

Question: Increased use of technology and differences in utilization and practice patterns have been identified as possible reasons for the rapid rise in health care costs. How will your study on geographic variation impact on this problem?

Answer: We recently announced in the Federal Register that ASPE is soliciting grant proposals to develop and conduct a program of research and analysis pertaining to geographic variations in health care expenditures. If we receive a good proposal for an indepth analysis of geographic variation using such variables as costs, illness, utilization, etc. we will in all likelihood obtain useful information on differences in utilization and practice patterns and the relationship to rising health care costs.

REDUCTION IN "OTHER SERVICES" RESEARCH

Question: Please explain the reason for a reduction of $704,000 in the Other Services category.

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Answer: The overall reduction in funding for Policy Research is consistent with the Administration's effort to hold discretionary spending as low as possible. The reduction reflects a shift away from large scale multi-year experiments. We are continuing to phase-down these large projects — notably the Health Insurance Experiment and the Monthly Reporting project — as they are completed. These large demonstrations are being replaced by smaller, short-term projects designed to respond to more immediate needs for policy information. This allows us to reduce funding.

This object class category represents contracts. The decrease in contracting obligations is a result of the overall reduction in funding from $9,750,000 in FY 1985 to $6,000,000 requested for FY 1986. The precise mix between contracts and grants (see answer to next question) is determined largely by the particular projects involved each year. Contracts decrease less than grants because we plan to fund our two largest FY 1985 projects — the Health Insurance Experiment and the Institute for Research on Poverty — at a lower level in FY 1986, and these projects happen to be grants.

GRANTS, SUBSIDIES AND CONTRIBUTIONS

Question: You are reducing grants, subsidies and contributions by $3,021,000. Provide the Committee with all grants, subsidies and contributions awarded in FY 1985 thus far. Which grants, subsidies and contributions will not receive funding in FY 1986?

Answer: The following grants have been awarded as of 3-30-85:

TITLE	AMOUNT	ORGANIZATION
Health Insurance Experiment	$3,036,984	The RAND Corp.
Measure of Case Mix and Quality of Care for the Study of Graduate Medical Education	$ 286,242	The RAND Corp.
Multiregional Policy Impact Simulation Model	$ 399,795	Boston College
Small Grants Program	$ 248,265	University of Wisconsin
Alternative Approaches to Conservatorship and Protection of Older Adults	$ 83,869	University of Southern California
The Role of Employer Benefits in the Economic Safety Net	$ 69,783	University of Utah
A Blueprint for Reform of Social Services	$ 34,900	American Society of Local Officials

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TITLE	AMOUNT	ORGANIZATION
Teenage Fathers: Barriers and Inducements to Family Involvement	$ 94,467	Fresno County Department of Social Services
Analysis of the Relationship of Research to the Policy Development Process in HHS	$ 15,000	Policy and Management Association

Although some of the work under the above grants will be performed in FY 1986, only one is scheduled for funding in FY 1986. Most Policy Research projects involve one-time awards. The one exception is the Health Insurance Experiment (HIE), a multi-year project in the table above nearing conclusion. The HIE is scheduled to receive $1.5 million in FY 1986.

Questions Submitted by Senator Daniel K. Inouye

POVERTY RELATED RESEARCH

Question: The number of persons whose income is at or below the poverty level has increased over the past four years. A recent T.V. network report depicted the plight of the working homeless; that group of persons who are trying to remain self-sufficient but cannot afford housing. What research is being done on poverty-related issues? What is currently being funded, and what are the projections for Fiscal Year 1986? How are research findings being disseminated?

Answer: A wide variety of poverty-related projects are currently being funded through the Policy Research Program. This is illustrated by the following list of topics being investigated by ongoing projects:

- Investigation of the relationships between the living arrangements, employment, schooling, and welfare recipiency of young women.
- Research on the labor market and program participation of Hispanics, immigrants, and southeast Asian refugees.
- Research on the relative economic status of various demographic groups, such as the aged, youth, and women, over the period 1940-1980.
- Examination of the first twenty years of the War on Poverty through papers presented at a major conference in December 1984 co-sponsored by the Department and the Institute for Research on Poverty (the conference proceedings will be published in a book).
- The University of Michigan's Panel Study of Income Dynamics, the longest-running longitudinal survey of economic behavior and income dynamics.

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- A wide-ranging study of low-wage labor markets in three priority areas: (1) obtaining a detailed picture of the characteristics of jobs in this market, (2) obtaining a comprehensive picture of trends, and (3) examining the behavior of employers active in this market.

- A comprehensive study of policy options for reducing long-term welfare dependency focusing on possibilities for targeting resources on likely long-term recipients.

- A survey of absent parents to improve child support enforcement activities.

- An assessment of assistance programs and eligibility issues for Central American refugees.

One of our research priorities is examination of options to address the plight of the homeless. The Institute for Research on Poverty, working with the city of Minneapolis, is addressing:

- The extent to which various public and private programs can reduce the number of individuals in a community who became homeless.

- The extent to which public or private policies help individuals "recover" from homelessness.

- The psychological and physical obstacles to reversing homelessness as contrasted to social conditions.

- The extent to which programs help ameliorate the problems the homeless face in day-to-day living.

We have also performed evaluations of innovative feeding, food bank and shelter programs for the homeless. We distributed our findings widely to help communities start and operate effective programs.

Additional FY 1985 and FY 1986 research will examine:

- The relative economic status of blacks including a focus on black male employment.

- Disability and long-term trends in health status.

- Income transfers and welfare dynamics including child support enforcement.

- Economic status and program participation of Hispanics and American Indians.

Finally, the Institute for Research on Poverty will continue its program providing small grants to researchers at other institutions. Specific grant topics for FY 1985 and FY 1986 will depend on applications. A listing of recent poverty-related grants follows:

- "AFDC: An Empirical Examination of the Forces Behind the Growing Caseload." Laurie Bassi, Georgetown University.

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- "Child Support Enforcement as a Means of Reducing Welfare Dependency and Poverty." Philip Robins, University of Miami.

- "Issues of Poverty: A Life-Cycle View." Kathryn Anderson, Richard Burkhauser, and J. S. Butler, Vanderbilt University.

- "Analyzing 'Trickling Down': How Labor Market Opportunities among the Poor are Affected by General Economic Growth." Rebecca Blank, Princeton University.

- "A Longitudinal Analysis of Nonparticipation in the Food Stamp Program by Eligible Households." Richard Coe, University of Notre Dame.

- "Sex Role Socialization and Economic Attainment: An Empirical Investigation." Mary Corcoran and Paul Courant, University of Michigan.

- "Working Off of Welfare: The Earnings Route to Self Sufficiency." David Ellwood, Harvard University.

- "Poverty in the Press: News Media, Public Opinion, and Policy Toward the Poor." Robert Entman, Duke University.

- "Changing Family Structure and Government Policy for the Defeminization of Poverty." Thomas Knieser, University of North Carolina and Marjorie McElroy, Duke University.

- "Social Security and the Wealth Holdings of the Poor." Edward Wolff, New York University.

Research findings are disseminated in many ways. Much research is used in writing reports to Congress on various subjects, such as likely impacts of raising the retirement age or allowing earnings sharing in social security or on assistance programs for Central American refugees. Most grantees publish their findings in professional journals and research often results in conferences and books. All reports are made available through the National Technical Information Service, and many through Project SHARE, a clearinghouse oriented toward State, local and private providers of human services. Periodic mailings listing recent research results and indicating how to obtain the paper are made to interested researchers and individuals involved in developing policy. For particularly significant reports, such as the Final Report of the Seattle-Denver Income Maintenance Experiment, both a targeted mailing and announcements in various professional journals were used. For example, the results of the December 1984 conference on poverty and policy will be published in a book in early 1986. For particularly policy-relevant projects, briefings are held for executive and legislative branch staff.

PREVENTIVE HEALTH SERVICES RESEARCH

Question: Hospital personnel report that they are currently experiencing a dramatic increase in census with a high proportion of very ill patients. This is following a period in which hospitals

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across the country reported low censuses, bed closings and the laying off of staff. What studies are being conducted to investigate the effects of cost-sharing on the utilizations of preventive health services and its long-term effect?

Answer: While some Policy Research projects touch on the areas of prevention and utilization, the Public Health Service assumes primary responsibility for this research. HCFA also has a few studies in this area including a demonstration project which is testing methods of delivering primary and preventive care services to medically underserved recipients. This study is designed to assess the potential for shifting care from hospital emergency rooms to municipal health clinics.

While we are not heavily involved in studies on the utilization of health care services, we are currently conducting a Congressionally mandated study on some of the indirect effects of cost sharing on utilization of general health services. This project involves the examination of Flexible Spending Accounts (Cafeteria Plans). The Health Insurance Experiment (HIE) has also produced data on the utilization of preventive health services in the context of differing coinsurance and deductibles under health insurance policies. The HIE findings in this area are not yet final, but preliminary results indicate that high coinsurance reduces utilization of both preventive and other health services significantly, with little or no impact on long-term heaalth status.

HEALTH INSURANCE EXPERIMENT

Question: In the Health Insurance Experiment (HIE), started in 1972, which examined the effects different consumer costsharing arrangements have on health care utilization, it was found that HMOs practice a different style of health care treatment compared to the fee-for-service sector. In what ways do the health care treatments differ?

Answer: The HIE data show that the fee-for service system controls costs by reducing contacts with the system, although use is unlimited. Patients make fewer visits and have fewer hospital admissions when they pay part of the cost. HMOs control costs with a lower intensity of treatment. Specifically, HMOs achieve savings though lower hospital admission rates. Both this study and other studies have reached this conclusion. The HIE study, however, used experimental design in establishing enrollment and thereby controlled for confounding factors such as self-selection bias among HMO enrollees.

SUBCOMMITTEE RECESS

Senator WEICKER. This will conclude the testimony for today. The subcommittee will stand in recess.

[Whereupon, at 11:10 a.m., Tuesday, April 30, the subcommittee was recessed, to reconvene at the call of the Chair.]

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STATEMENT OF PHILLIP N. HAWKES

Mr. Chairman, members of the subcommittee, I appreciate the opportunity to discuss the refugee and entrant assistance programs of the Department of Health and Human Services, and the budget that we are proposing for FY 1986.

Title IV of Immigration and Nationality Act and Section 501 of the Refugee Education Assistance Act of 1980 (Public Law 96-422) authorize a comprehensive program of cash and medical assistance and social services for refugees and Cuban and Haitian entrants. At the end of fiscal year 1984, 49 States, the District of Columbia and Guam had approved State plans for refugee resettlement. In addition, 33 States and jurisdictions currently provide assistance and services on behalf of Cuban and Haitian entrants.

The FY 1986 budget request for refugee and entrant assistance is $316,587,000. This request is for a single appropriation for the Refugee Assistance and Cuban/Haitian Entrant Programs and is premised on Congressional reauthorization of the refugee program.

The FY 1986 budget request for Refugee and Entrant domestic assistance represents a decrease of $88,759,000 from the $405,346,000 appropriated under the Continuing Resolution for FY 1985. This reduction reflects an anticipated decline in cash and medical assistance, a decrease in social services funding and elimination of Federal funding for targeted assistance and education assistance programs. This is due to the anticipated reduction in refugees likely to participate in these programs given the declining flows of refugees into the United States, our efforts to enhance refugee self-sufficiency and employment, and the increasing ease with which communities are able to absorb new refugee arrivals.

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The targeted assistance program was initiated in FY 1982 in response to the temporary surge of entrants that had occurred in 1980, and it was continued during FY 1983-85 for both entrants and refugees, responding also to the large inflows of refugees which had occurred during FY 1980-1982. By the end of FY 1985, over $200 million in targeted assistance funds will have been awarded. Meanwhile, refugee flows have been significantly lower during the last few years, and the program is no longer necessary.

The fact that we are not requesting funds for education assistance also reflects the reduced flows of recent years. In FY 1982, nearly 100,000 refugees entered the United States. For FY 1986, only 68,000 refugee admissions are anticipated. Since FY 1980, over $100 million has been awarded on behalf of refugee school children. We feel that the funds which have been provided during the past six years have built the capacity necessary to address the needs of refugee children. We would also note that many refugees are working and paying taxes to help support their local school systems, on the same basis as other residents of the communities in which they live.

The Department will continue to support a policy that would make voluntary resettlement agencies responsible for the basic needs of refugees during their first 90 days in this country. Funding for this purpose is included in the budget request of the Department of State for distribution to voluntary resettlement agencies.

The concentrated efforts of these agencies during a refugee's critical first 90 days in this country are expected to increase the opportunities for early financial independence and avoid dependence on welfare programs.

There are four activities proposed under the refugee and entrant programs in FY 1986: State Administered Programs, Preventive Health, Voluntary

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Agency Programs and Federal Administration. These may be summarized briefly as follows:

1) State Administered Programs. We are requesting $299,705,000 under this activity in FY 1986 which will provide Federal funds to reimburse the State's share of cash and medical assistance provided to refugee/entrants eligible for and receiving benefits under the programs of Aid to Families with Dependent Children (AFDC), Medicaid (Title XIX of the Social Security Act), and Supplemental Security Income (SSI). Federal funds will be made available for such costs for up to 36 months after the individual's arrival in this country.

In FY 1986, 100% Federal funding will continue to be made available for non-AFDC and non-Medicaid eligible refugees/entrants for cash and medical assistance provided to refugees/entrants, who meet State income tests, for the first 18 months from the date of arrival in this country. For the second 18 months, refugee/entrants eligible for State or local General Assistance programs will receive cash and medical assistance on the same basis as non-refugees with full Federal reimbursement.

The State Administered Program activity will also make funds available for refugee/entrant social services programs which include primarily job placement services and English language training activities aimed at assisting refugee/entrants to achieve economic self-sufficiency, and for services for unaccompanied minor and related administrative costs under the State administered programs.

2) Preventive Health. We are requesting $9,032,000 in FY 1986 to support two basic functions related to the health care for refugees. First, $2,200,000 will be made available for monitoring the adequacy of medical screening and assuring appropriate follow-up and treatment of refugees with diseases of public health concern. This work will be

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conducted by Centers for Disease Control (CDC) personnel stationed overseas and at ports of entry. They will work tc assure the continued high quality of medical screening and disease surveillance overseas and the inspection and State notification procedures at ports of entry. They will also continue to operate a computer system for refugee medical records and a tracking and notification system for refugees with class A/B tuberculosis, class B venereal disease, and class B leprosy.

The budget request also includes $6,832,000 to cover a modest grant program to support State and local health agencies which conduct health assessments and immediate follow-up care for a variety of conditions including skin infections, intestinal parasites, malnutrition, and anemia. In addition this activity will provide support to state and local health departments for follow-up and preventive treatment of refugees found to have tuberculosis infection.

3) Voluntary Agency Programs. For FY 1986, ORR proposes to decrease the Federal matching payment to voluntary agencies from a maximum of $1,000 to $500 per refugee to further stimulate greater private sector financing. This program originated to provide additional funding for an alternate initial resettlement approach for Soviet and East European refugees during a period of unusually high arrival rates in 1979 and 1980.

The voluntary agency program is not intended as a supplemental program to State administered assistance, but is an alternative program to provide national voluntary resettlement agencies with matching Federal funds for resettlement assistance and services for refugees. The principal objective is to enable the refugees to become self-supporting and independent members of American society. The essential services required are case management, job placement, and maintenance support for up to

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four months, as needed. Additional services which may be provided include English Language Training, medical assistance, and acculturation.

Funding is provided for this activity in lieu of regular State administered cash and medical assistance and social services. For FY 1986 we are requesting $2 million for this program activity.

4) Federal Administration. The Office of Refugee Resettlement (ORR) was established by the Refugee Act of 1980 to be responsible for the management of the domestic refugee resettlement program.

We are requesting $5,850,000 in FY 1986, a reduction of nearly $700,000 from the FY 1985 level, which reflects a staff reduction of 2 positions and a 5% pay reduction as proposed by the administration. These funds are used to administer the annual appropriation for refugee and entrant assistance, to monitor the recipients of Federal grants under the Refugee Resettlement Program and the Cuban/Haitian Entrant Program, both fiscally and programmatically, and to continue national initiatives (such as planned secondary resettlement, alternative programs for cash and medical assistance, English language training and employment standards) in response to the problems of domestic resettlement.

I wish to thank you for the opportunity to address this subcommittee. I am prepared to respond to questions at this time.

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